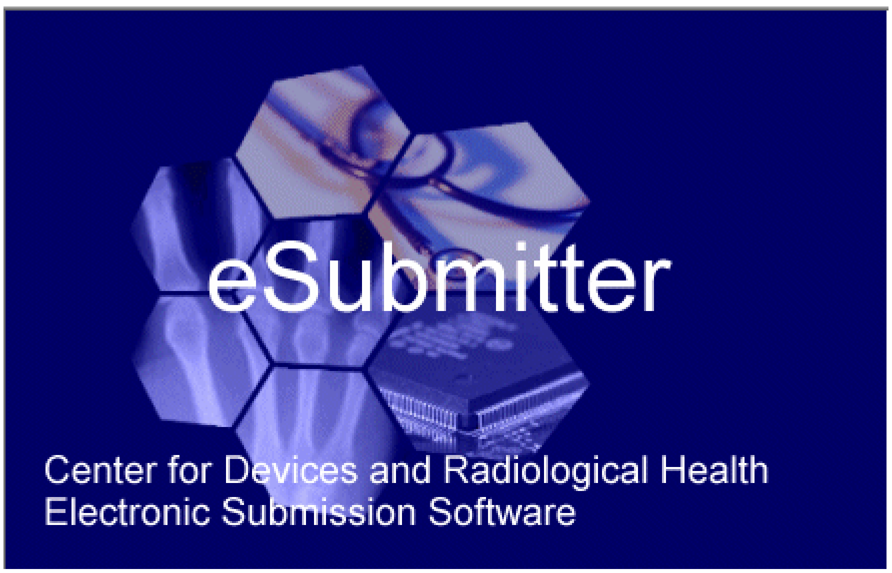
Center for Devices and Radiological Health

CeSub eSubmitter User Guide



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DOCUMENT CHANGE RECORD

Version Number	Date	Description
Version 1.0	May 26, 2004	OIVD Pre-Pilot Release (Software v1.00.00)
Version 1.1	August 27, 2004	Updated to reflect the enhancements incorporated in the Official OIVD Pilot Release (Software v1.00.01)
Version 2.0	March 15, 2005	Updated to reflect enhancements incorporated into the CeSub Pilot Release (software version 1.10). Updated for applicability to OIVD and Radiological Health.
Version 3.0	June 24, 2005	Updated for corrections and additional descriptions. Also updated to reflect the enhancements in Software versions 1.02.00 and 1.03.00.
Version 4.0	October 31, 2005	Updated to reflect the enhancements in software versions 1.04.00 through 1.07.00
Version 4.1	March 2, 2006	Revised the proxy server settings.

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1. INTRODUCTION

The Center for Devices and Radiological Health (CDRH) electronic Submission (CeSub) eSubmitter tool is a free program that allows program participants to electronically complete and submit information for a 510(K) device or radiation emitting product to the Office of In Vitro Diagnostic Device Evaluation (OIVD) or Radiological Health. This tool is intended to automate the current paper submission process, allowing for quicker completion once users are accustomed to the software, as well as speed up the filing process with CDRH. The eSubmitter software requires completing a series of questions in electronic forms and allows attaching documents when additional information is needed.

Filing product reports for radiation emitting products is required by law. The CeSub eSubmitter software replicates several of these reporting guides, which have been available in hard copy for decades. The electronic reporting guides available in eSubmitter are still under development, and the software is regarded as a pilot program. If using the eSubmitter software is not desirable, you may continue to complete hard copies of the report, which are available as Adobe Portable Document Format (PDF) and/or Microsoft Word documents at www.fda.gov/cdrh/comp/eprc.html.

1.1 ABOUT THIS GUIDE

The instructions in this guide provide detailed information for installing the CeSub eSubmitter software into a computer with a **Microsoft Windows operating system. In addition, this user guide assumes familiarity with terms associated with using a computer (e.g. clicking and double-clicking).**

This guide is organized into six sections (in addition to this one):

Section 2 explains the requirements for running CeSub eSubmitter software, installation instructions, proxy server instructions, and uninstall instructions.

Section 3 provides instructions for quickly starting up the software and setting up a PDF viewer.

Section 4 provides descriptive information about the software and various dialog boxes that you will see.

Section 5 provides instructions for completing an actual report and getting it ready to submit to CDRH.

Section 6 provides information for getting technical support for the eSubmitter software.

Section 7 contains frequently asked questions.

Section 8 is an index for the contents of this guide.

Please note that the screens used in this document are **examples** of what you might see while using the software. However, they may not appear exactly as shown.

In this document, titles and contents of dialog boxes appear in this format: **Text.**

This convention is used so that you may easily differentiate what you see on your computer screen from the text in this user guide.

In addition, the terms submission, report, and submission report are used interchangeably in this guide to refer to a submission report.

2. SOFTWARE INSTALLATION

2.1 SYSTEM REQUIREMENTS

- Windows Operating System
- Adobe Acrobat Reader v5.0 or greater.
- 30 MB of disk space
- Access to a Compact Disk-Recordable drive (CD-R Drive)
- Software capable of viewing HTML, such as a Web browser, Microsoft Word or Adobe Acrobat (full install version, not the Reader)

2.2 UNINSTALL INSTRUCTIONS

Before installing CeSub eSubmitter, **uninstall any other version of the software**.

Note: If you do not have a previous version of eSubmitter or if you have eLaser Pilot Software, proceed to installing the current version of eSubmitter software.

To uninstall a previous version of eSubmitter:

1. Use Windows Explorer to navigate to the label for the computer's installed hard drive, e.g., **Local Disk (C:)**. For example, on a computer with Windows 2000:
    - Open Windows Explorer.
    - Double-click **My Computer** to display its contents.
    - Look for the label of the computer's installed hard drive. For example, **(C:)**.
2. Double-click on the label for the hard drive to display its contents.
3. Navigate to and double-click to open the **Program Files** file folder.
4. Navigate to and click to open the **eSub** file folder.
   You will see the folder's contents in the pane on the right-hand side of the screen.
5. Double-click on the **Uninstall.exe** file, and follow the instructions provided.

Note: If you do not see the **Uninstall.exe** file:
- Locate and double-click to open the **JExpress** file folder.
- Double-click on the **uninstall.bat** file, and follow the instructions provided.

6. When the previous version has been uninstalled, you are ready to install the current version of the CeSub eSubmitter software. See the following procedure.

2.3 INSTALLATION INSTRUCTIONS

CeSub eSubmitter software is available for downloading from the web at https://www.fda.gov/cdrh/cesub/.

To install the latest version of the CDRH CeSub eSubmitter software from this web page:

1. Click the link for **Download the CeSub eSubmitter Software**.
2. Follow the instructions provided. Following the instructions, the software will be installed locally on your hard drive in **C:\Program Files\eSub**.

Notes: 1. You can change the location where the software is installed by changing the file path on the **Installation Directory** dialog box when it appears.
2. The software may be installed on a network. However, the software was not intended to be used by multiple users at the same time. As long as it is used only by one individual at a time, there is no issue with installing the software on a network.

To install the latest version of the CDRH CeSub eSubmitter software from a CD-ROM:

1. Windows Explorer should be open on your computer's desktop.
2. Insert the eSubmitter CD-ROM in the CD drive of your computer.
3. Navigate to the directory of the CD drive, if you do not see it on your screen. For example, on a computer with Windows 2000:
   - Open Windows Explorer.
   - Double-click My Computer to display its contents.
   - Look for the label for the CD drive. For example, **(E:)**.
4. Double-click on the label for the CD drive to display its contents.
5. Double-click on the **jinstall.exe** file.
6. Follow the instructions provided. Following the instructions, the software will be installed locally on your hard drive in **C:\Program Files\eSub**.

Note: You can change the location where the software is installed by changing the file path on the **Installation Directory** dialog box when it appears.

7. When the installation is complete, remove the CD-ROM from the CD drive.

Note: The software may be installed on a network. CeSub eSubmitter has a file locking option that you set to prevent users from accidentally overwriting the work of another. For details, see *Networking* in *Preferences* on page 20.

2.4 PROXY SERVER INSTRUCTIONS

If you are using a proxy server to connect to the Internet, then you will need to change the application's properties file (**eSubmitter.properties**) to reference the server. See your System Administrator for help in changing the properties file.

The properties file is located in the application's JExpress subdirectory (**Program Files\eSub\JExpress)**. Add the following switches **before** the -cp switch:
-DproxySet=true -DproxyHost=[proxy_host] -DproxyPort=[proxy_port]
(replace [proxy_host] and [proxy_port] with the appropriate information for your configuration).

If the proxy server requires a user id and password, add the following two properties to the **update.control** file that's also located in the **JExpress** subdirectory:

proxyUserName=
proxyPassword=

3. GETTING STARTED

After you have successfully installed the CeSub eSubmitter software, you are ready to start up the application and create a new report. In addition, as you use the software and answer questions to complete your report, you will have the opportunity to attach PDF files to supply additional information, as well as view PDFs of your attachments. Before you are able to attach PDFs, you must specify the application that you will use as your PDF viewer. (Generally, Adobe Acrobat is used as the application for viewing PDFs.). The first time that you try to attach a PDF, you will see a confirmation dialog box asking you to specify the PDF viewer.

This section provides instructions for starting up the software and setting up the PDF viewer.

3.1 STARTING THE SOFTWARE

To start up the CeSub eSubmitter application:

1. Click **Start**, and select **Programs > CeSub eSubmitter > eSubmitter.**

   You will see a **Welcome** dialog box, which provides an introduction to the application. You can set the **Welcome** dialog box to no longer display at application startup. For this setting, click to clear the **Show this screen at Startup** check box within the dialog box.

2. When you are finished reading the **Welcome** dialog box, click **Close**.
3. You will see a **Registration Dialog** box. An example is shown in *Figure 1*.

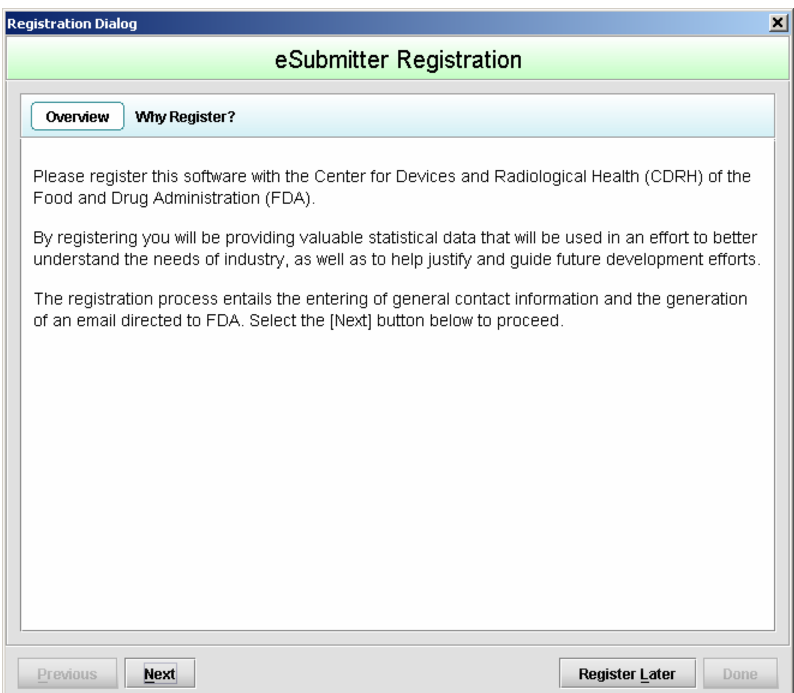


Figure 1: Example of the Registration Dialog Box

4. Click **Next** to continue the registration process. Or, click Register Later to register at another time. If you click **Next**, you will see a dialog box asking you to enter your contact information.
5. On the **Contact Information** dialog box, enter the information requested. Required entries are indicated by blue dots. Click **Next**. You see an **Address Information** dialog box.
6. On the **Address Information** dialog box, enter the information requested. Required entries are indicated by blue dots. Click **Next**. You see a **Generate Email** dialog box.
7. On the **Generate Email** dialog box, you see a summary of the information you entered. If the information is correct, click **Next**. If the information is not correct, click **Previous** until you return to the screen that you need to correct.
8. Click **Generate Email** in the dialog box. You will see an email.
9. Click Send in the email. You see a **Check Results** dialog box.
10. Select the button corresponding to either **Yes the Email was sent correctly** or **No there was a problem**.
11. Click **Done** if the email was successful and to complete the registration process.

If the eSubmitter software has been updated and you are connected to the Internet, you will see an **Application Update Message** to notify that the software has changed. See *Figure 2* for an example.

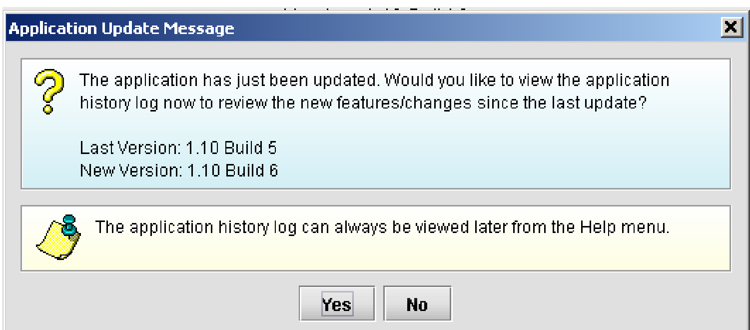
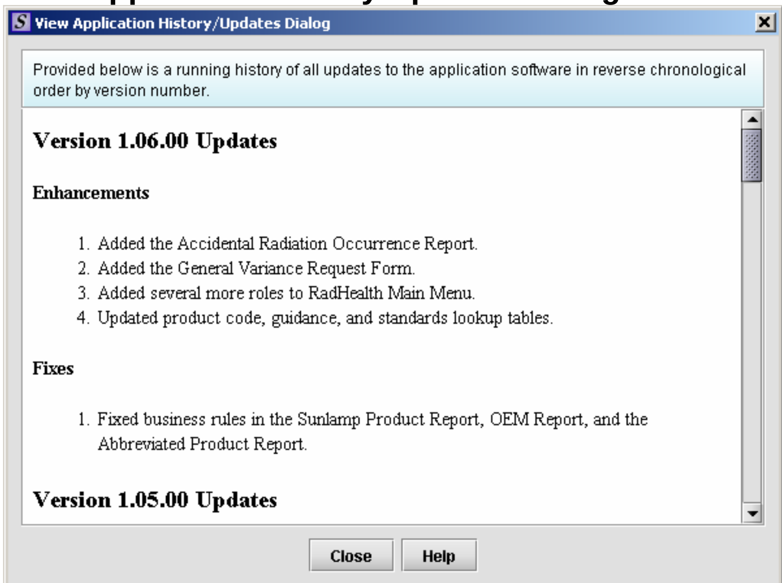


Figure 2: Example of an Application Update Message

12. On the **Application Update Message**:
    - Click **No** if you do not wish to see a list of the changes to the software. You can review the changes at a later time if you wish. For more information see View Application History Log in the section, *Menu Bar - Help*, beginning on page 32.

- Click **Yes** if you do want to review a list of changes to the software. You see the **View Application History/Updates Dialog** box. See



- *Figure* 3 for an example.

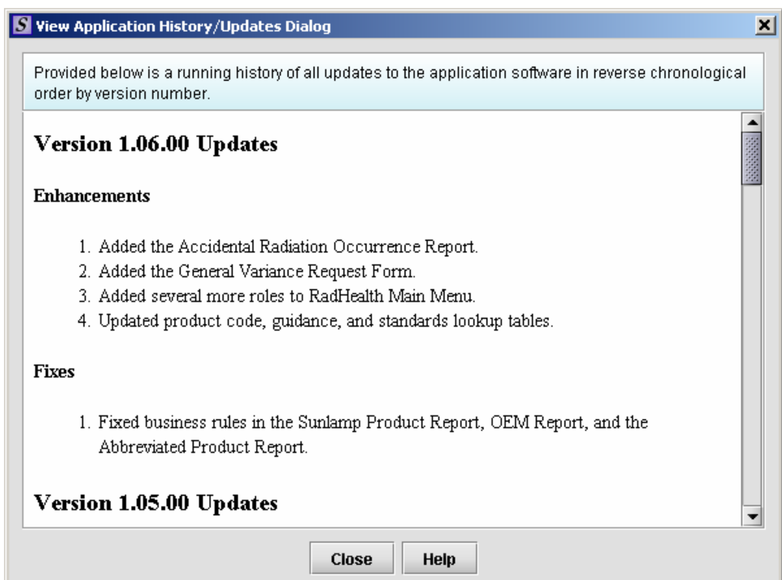


Figure 3: Example of View Application History/Updates Dialog Box

⇒ Click **Close** when you are finished reviewing the list of changes. The dialog box closes.

13. Next, you see the **Open Report Data Dialog** box. See *Figure 4*. This dialog box allows you to select an existing submission or begin a new one. As you create new reports, they are shown in this dialog box as a list of all the available submissions with a comments area for viewing additional information on the selected submission. However, if this is the first time that you started up the application after installing the software, the list will be blank as shown in *Figure 4*.

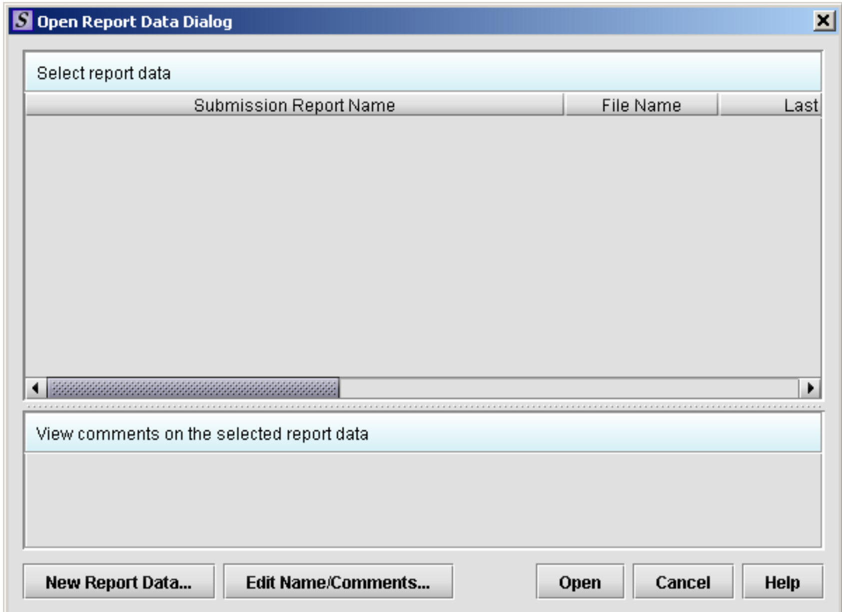


Figure 4: Open Report Data Dialog Box

14. Look at the bottom of the **Open Report Data Dialog** box. (See *Figure 4*.) You will see five option buttons that are described below:

New Report Data...
Clicking this button displays the **New Report Dialog** box, which allows the creation of a new submission report file. The dialog box displays areas for the report type, as well as areas for entering a descriptive name for the submission, a file name, and comments. Any descriptive name may be assigned to a new submission report file, as long as it is unique to the submission list and not blank. It is a good idea to use a name that distinctly identifies the report. Use alphanumeric characters for file names.

Edit Name/Comments
Clicking this button displays the **Edit Name/Comments Dialog** box, which allows the descriptive name and comments of the selected submission report file to be changed. The dialog box displays the current submission name and comments. Any name can be assigned to a submission report file, as long as it is unique to the submission list and not blank. (For complete information on creating or editing a submission, see *Preparing a Submission*, beginning on page 43.)

Open
Clicking this button closes the **Open Report Data Dialog** box, and opens the selected submission. In addition, double-clicking on a submission or pressing the **Enter** key while a submission is highlighted will also open the submission. (For complete information on creating or editing a submission, see *Preparing a Submission*, beginning on 43.)

Cancel
Clicking this button closes the **Open Report Data Dialog** box with no changes to the screen.

Help
Clicking this button displays the help text for the **Open Report Data Dialog** box.

15. If this is the first time that you started up the application after installing the software, click **New Report Data** to create a new submission. (That way, you will have a report open as you read the rest of this guide. You will also need to have a report open to set up your PDF viewer, which you will do in the next section.)
You see the **New Report Data Dialog** box as shown in *Figure 5*.

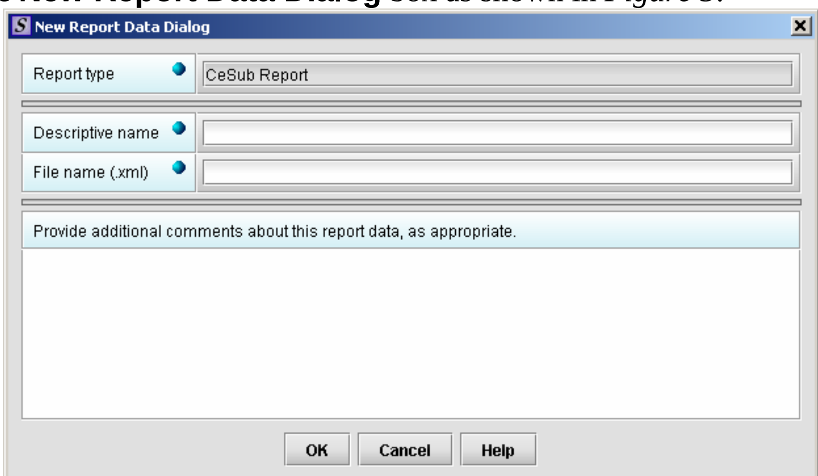


Figure 5: New Report Data Dialog

16. On this dialog box:
   - In **Descriptive name**, type a name for the report. Any descriptive name may be assigned to a new submission report file, as long as it is unique to the submission list and not blank. It is a good idea to use a name that distinctly identifies the report.
   - In **File name**, type the corresponding name for file. Use alphanumeric characters for file names.
   - **Report type** will already have the entry of CeSub Report. **Do not change this entry**.
   - In the comment section, type any additional information about the report that you wish.
   - Click **OK** when you are finished entering the information. The dialog box closes, and you see the **Open Report Data Dialog Box** (an example is shown in *Figure 4*) with your new report already highlighted. To select, click **Open** and you see the first screen of the report.

3.2 SETTING UP YOUR PDF VIEWER

To attach PDFs to your report, you must identify the application that you will use as your PDF viewer. (Generally, Adobe Acrobat is used as the application for viewing PDFs.) The first time that you try to attach a PDF in response to a question you will see a message asking you to specify the viewer. For ease in finding these instructions, they are placed in the beginning of the user guide. You will not need them until you try attaching a PDF to a question.

For information on responding to questions in the submission, see *Entering Submission Information*, beginning on page 48.

To set up the PDF Viewer:

1. The eSubmitter application should be open, a report should be displayed, and you should have tried to attach a PDF in response to a question. The software will try to generate a PDF of the blank report. You will see a confirmation dialog box asking you to specify the PDF Viewer (as shown in *Figure 6*).

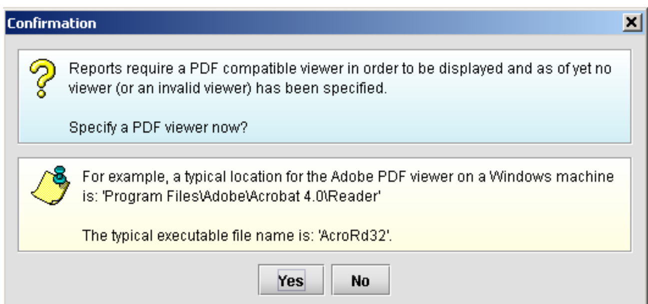


Figure 6: Confirmation Dialog Box

2. On this dialog box, click **Yes**. You see a dialog box similar to the one shown below:

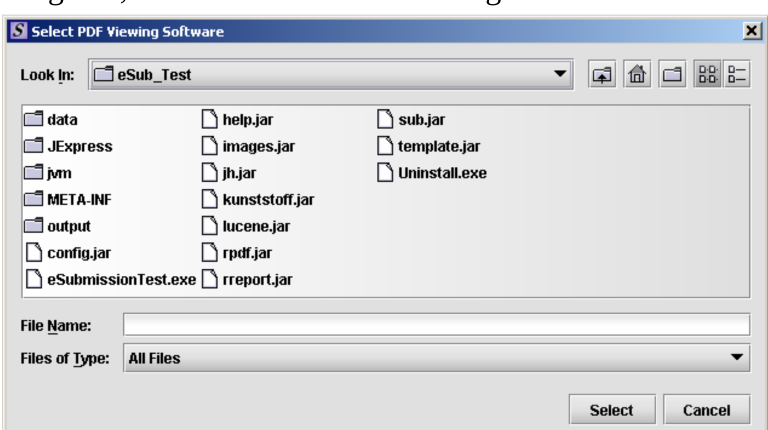


Figure 7: Select PDF Viewing Software

3. On this dialog box:
   - Click in the **Look In** box, and navigate to the file folder for Adobe. The location is usually:

Program Files > **Adobe** > **Adobe 5.0** (or 6.0, depending on the version that you have installed) > **Adobe**

- Click to highlight (select) **Acrobat exe**, and click Select. (See *Figure 8*.)

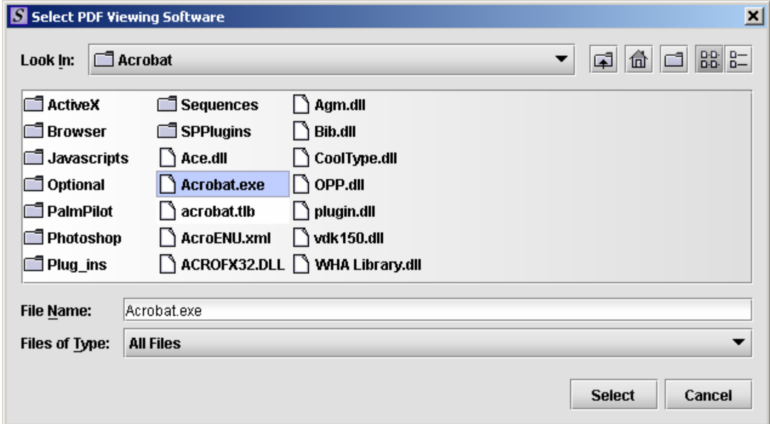


Figure 8: Select Acrobat.exe

4. The software will create a PDF of the blank report. After the PDF opens on your screen, close it without saving.
5. Go to section 4, *Interface*, beginning on 15 to learn about the different areas of eSubmitter software.

4. INTERFACE

4.1 APPLICATION WINDOW

This section describes eSubmitter's Application Window and its different parts.

The eSubmitter Application Window has two layouts that change the orientation of the text on the screen: **simple** and **expert**. When you first start up the application, eSubmitter opens in the simple layout with a screen view. This view shows only the current data entry screen and "hides" an outline tree (which is similar to a folder or directory tree structure in Windows). To navigate through the screens in a report, click the arrow buttons on the button bar, which is located at the bottom of the screen. See *Figure 9*.

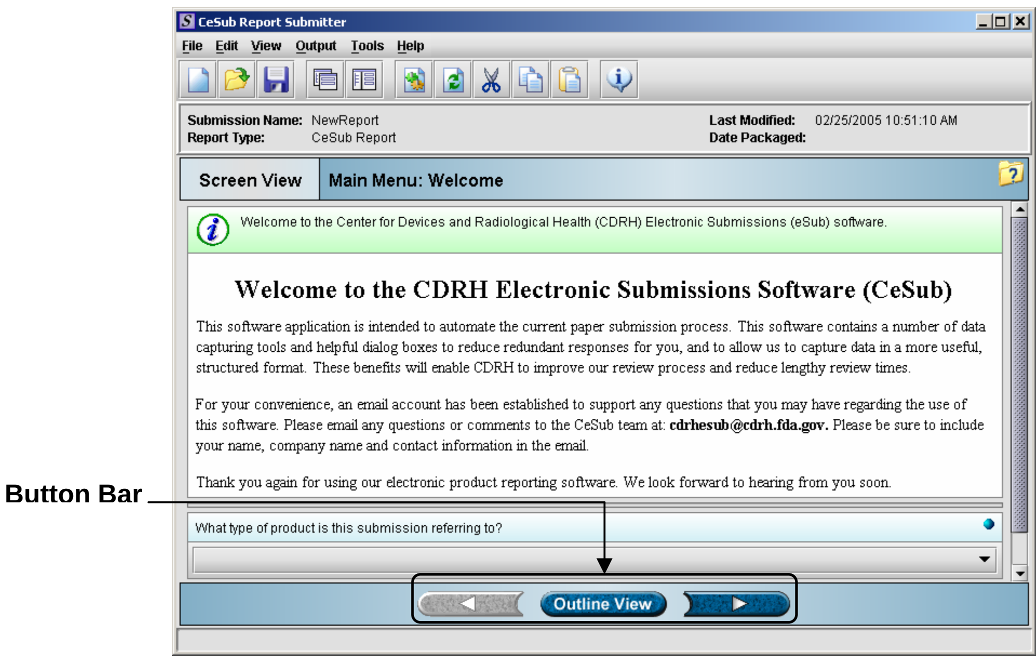


Figure 9: Simple Layout

The expert view allows the user to navigate through the form using an outline tree located on the left side of the screen. An example of the expert view is shown in *Figure 10*.

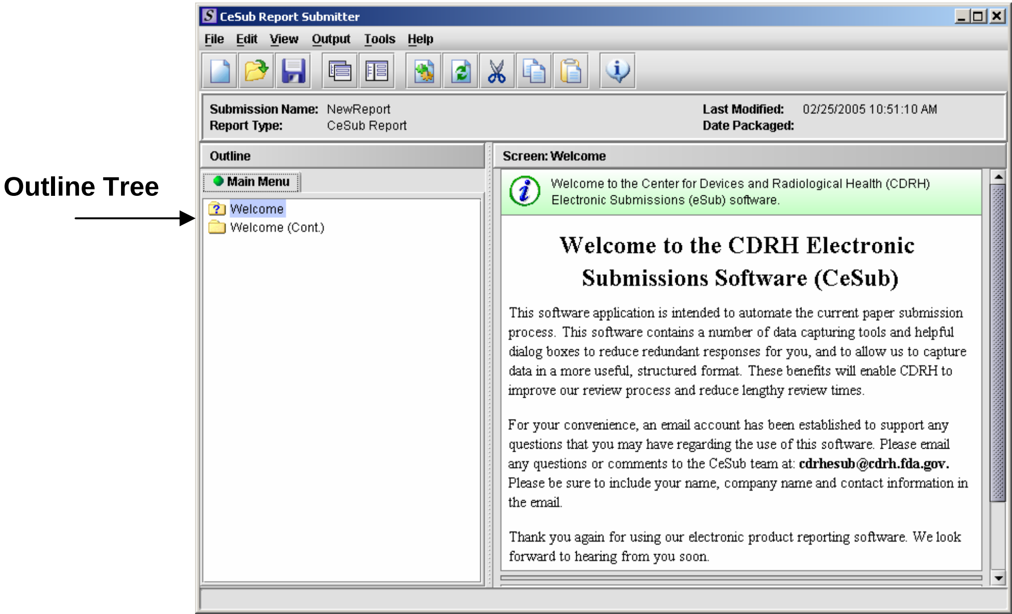


Figure 10: Expert Layout

Both layouts provide the same information. It is your choice as to which layout works best for you. You can switch between the two layouts very easily, as well as customize eSubmitter to open in the expert layout. For more information about simple and expert layouts, see *Menu Bar - View*, beginning on page 21. To learn how to change eSubmitter so that the application opens in the expert layout, rather than in the simple layout, see *Layout* in the User Preferences Dialog Box beginning on page 19.

The Application Window, whether in simple or expert layout, is divided into three parts, as shown in *Figure 11*.

- Menu Bar
- Tool Bar
- Primary Work Area

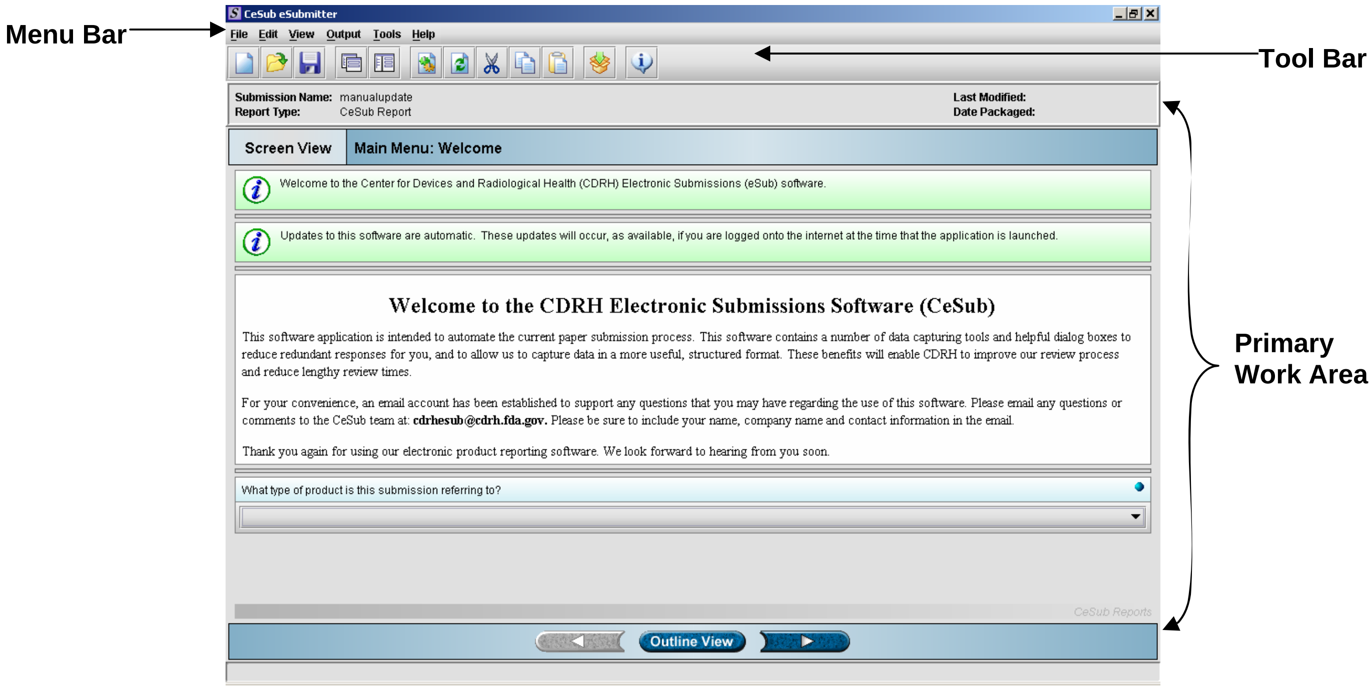


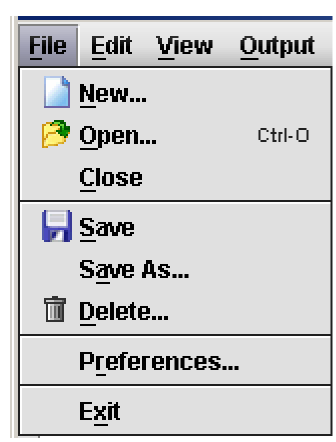
Figure 11: Parts of the Application Window

4.2 MENU BAR

The menu bar (see *Figure 11*) is a horizontal bar residing at the top of the application window that contains various drop-down menus (listed below):

- File (see page 17)
- Edit (see page 21)
- View (see page 21)
- Output (see page 24)
- Tools (see page 25)
- Help (see page 32)

4.2.1 Menu Bar - File



The **File** menu primarily provides an interface for operations that apply to a submission. Each command on the **File** menu is described below:

New – Displays the **New Submission dialog**, which allows a new (empty) submission to be created.

Open – Displays the **Open Submission dialog** box, which allows an existing submission to be selected and opened.

Close – Closes the submission that is currently open.

Save – Saves any changes within the open submission to permanent storage (e.g., to the hard drive).

Note: When a submission is open, all of the information associated with the submission is loaded into temporary memory. All data entry changes are recorded to this temporary memory.

Save As – Displays the **Save As Dialog** box, which allows a new submission report file to be created from the contents of the submission report file currently open (in other words, all the data from the open report is copied to create the new report). The dialog box displays areas for entering a submission name and comments. Remember that any name can be assigned to a new submission report file, as long as it is unique to the submission list and not blank.

Delete – Displays the **Delete Submission Dialog** box, which allows the opened submission report file to be deleted. The dialog box displays basic information about the submission for verification purposes.

Note: Once a submission is deleted, it is completely removed from the system. It is the responsibility of the submitter to maintain a record of all submissions. Therefore, verify that this submission was never transmitted to FDA or that it has been saved elsewhere before proceeding with the deletion.

Preferences – Displays the **User Preferences Dialog** box, which allows you to turn auto-save on or off, specify whether eSubmitter will open in the simple or expert layout, and set up the application for use on a network. See *Figure 12.*

- **Auto Save –** When this option is enabled**,** eSubmitter automatically saves your report while you work. You can also set the interval for how often you want to save your report. At default, auto-save is automatically turned on, and set to save files at 10 minute intervals.

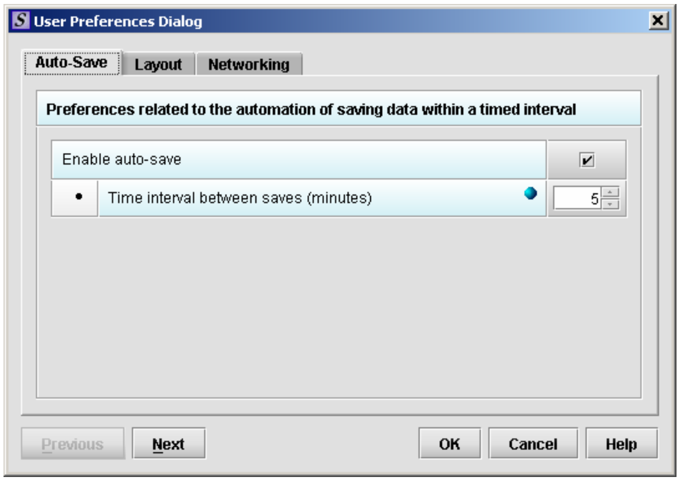


Figure 12: User Preferences Dialog Box

To change the auto-save option:

1. Click to select the enable auto-save checkbox (to turn auto save on) or click to clear the checkbox (to turn auto-save off).
2. If you cleared the checkbox, go to step 3. If you selected the checkbox (as shown in Figure 12),
   In the time interval box:
   - Enter the interval (in minutes) for often you want to save file.
   OR
   - Use the up and down arrows to select the interval.
3. If you want to change set the layout, click **Next** or the **Layout** tab. See the description for **Layout** below.
   OR
   - If you are finished and satisfied with your changes, click **OK** to close the **User Preferences Dialog** box.
   OR
   - Click **CANCEL** to close the **User Preferences Dialog** box without making any changes.

- **Layout –** allows you to set whether you want eSubmitter to open reports in the simple or expert layout when you start up the application. *See Figure 13.* At default, eSubmitter opens reports in the simple layout. For more information on the screen layouts, see the descriptions beginning on 21.

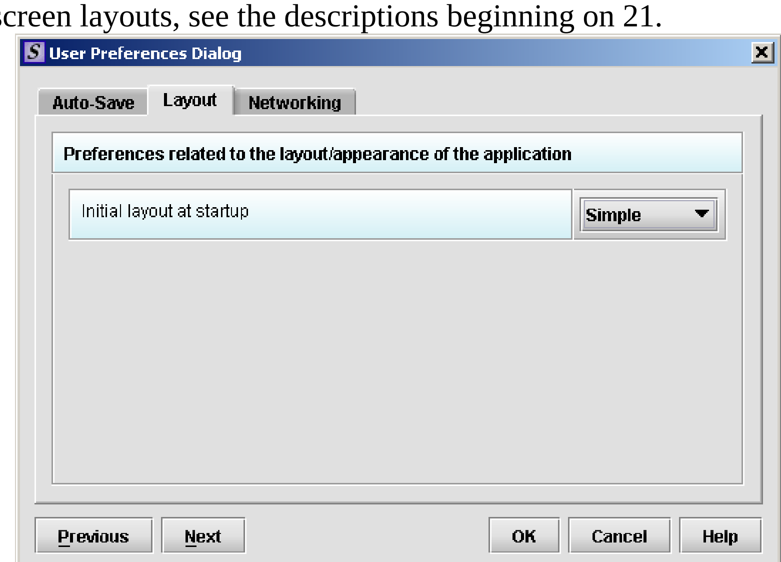


Figure 13: User Preferences Dialog Box, Layout Option

To change the layout when eSubmitter starts up:

1. In the initial layout box, click to select **Simple** or **Expert**.
2. If you want to change the settings for auto-save, click **Previous** or the **Auto-Save** tab. See the description for **Auto-Save** on page 18.
   OR

- If you are finished and satisfied with your changes, click **OK** to close the **User Preferences Dialog** box.

OR

- Click **CANCEL** to close the **User Preferences Dialog** box without making any changes.

- **Networking –** allows you to set file locking when using the software on a network. The application is primarily designed for use by one user at a time. However in an effort to help support those that wish to run the application from a network and want to prevent users from accidentally over-writing the work of another, a simple file locking strategy has been incorporated. By enabling file locking, a user will be warned if the file that they are attempting to open is currently in use by another. *See Figure 14*. At default, eSubmitter opens without file locking.

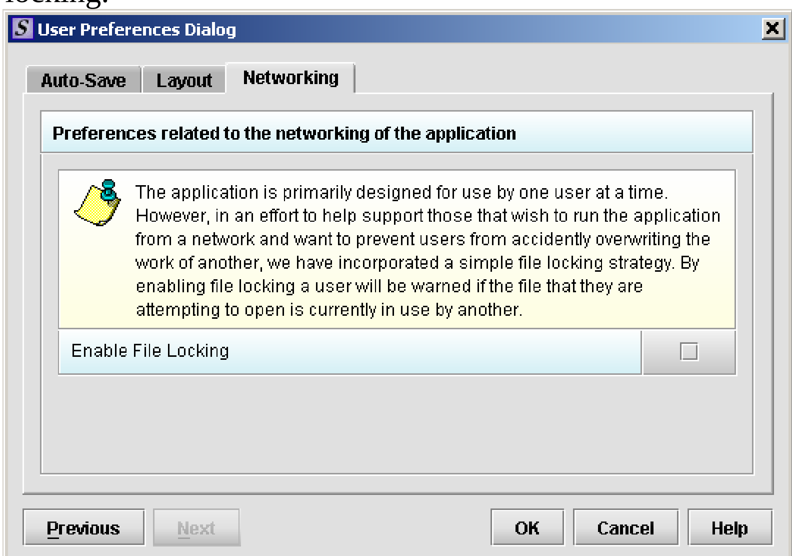


Figure 14: User Preferences Dialog Box, Networking Option

To enable file locking:

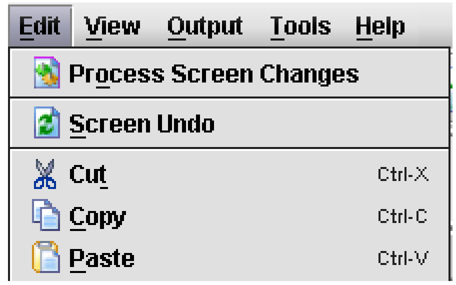
1. Click to select the **Enable File Locking** checkbox (to turn file locking on) or click to clear the checkbox (to turn file locking off).
2. If you are finished and satisfied with your changes, click **OK** to close the **User Preferences Dialog** box.

   OR

   - Click **CANCEL** to close the **User Preferences Dialog** box without making any changes.

Exit – Exits the application software.

4.2.2 Menu Bar - Edit



The **Edit** menu includes general purpose editing commands, which are described below:

Process Screen Changes – Processes your changes to screens without saving the report or selecting another node. This option allows you to see your changes quickly.

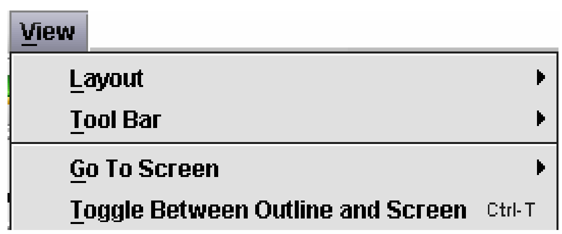
Screen Undo – Refreshes the data in all the data entries displayed within the screen area with their initial values before you made any changes.

Cut – Removes the selected text from within the data entry area that currently has the focus, and transfers it to the system clipboard.

Copy – Copies the selected text from within the data entry area that currently has the focus, and transfers it to the system clipboard.

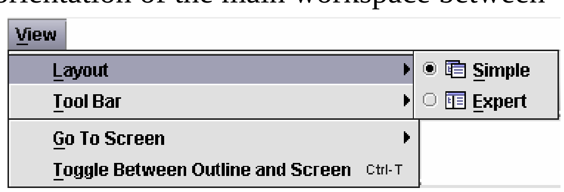
Paste – Pastes the text from the system clipboard into the data entry area that currently has the focus.

4.2.3 Menu Bar - View



The **View** menu includes general purpose commands for adjusting and moving around within the layout of the application window. Each command is described below:

Layout – Provides options for switching the orientation of the main workspace between two distinct layouts: **Simple** or **Expert**.



- **Simple** layout **–** Displays the current data entry screen and contains basic options for moving forward and backward through a report, one screen at a time. A view of the overall report outline is provided on a secondary screen.

  This layout is most useful when stepping through the report sequentially and when viewing the application through a lower resolution display (i.e., more area can be dedicated to the data entry screen).

Use the buttons on the Button Bar on the bottom of the screen to move through the report or to display the outline. See *Figure 15* for a Simple layout with a Screen view. See *Figure 16* for a Simple layout with an Outline view. Each time that you start up the program, eSubmitter will open in a Simple layout with a Screen view. You can change this setting so that eSubmitter opens in the Expert layout, if you wish. For instructions, see *Layout* in the User Preferences Dialog Box, beginning on page 19.

To switch between the screen view and the outline view, click the **Outline** and **Screen** buttons, respectively.

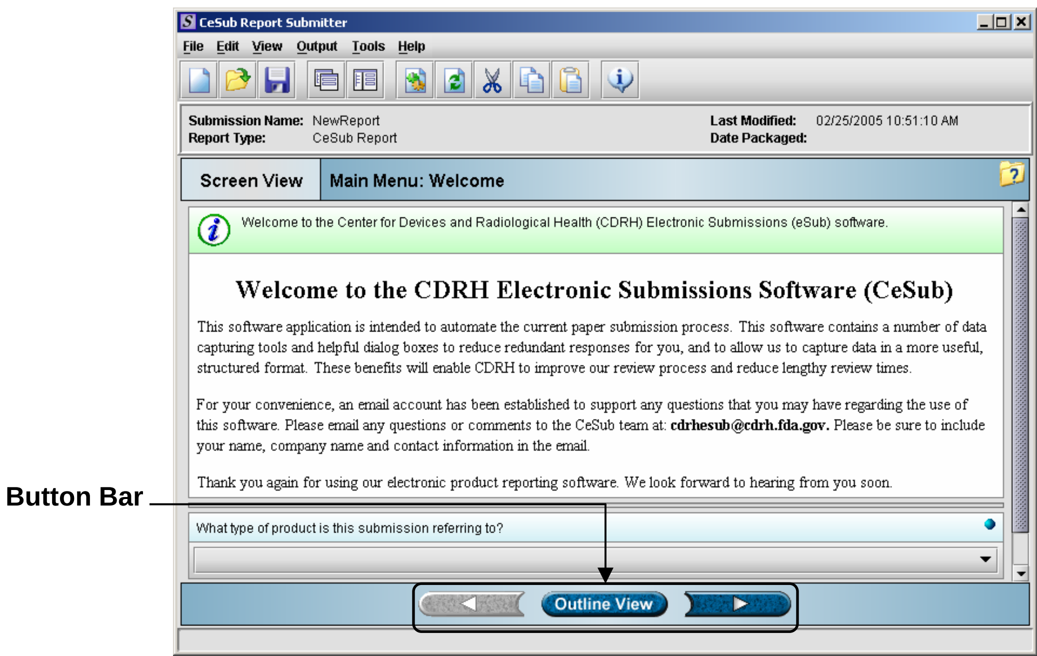


Figure 15: Simple Layout, Screen View

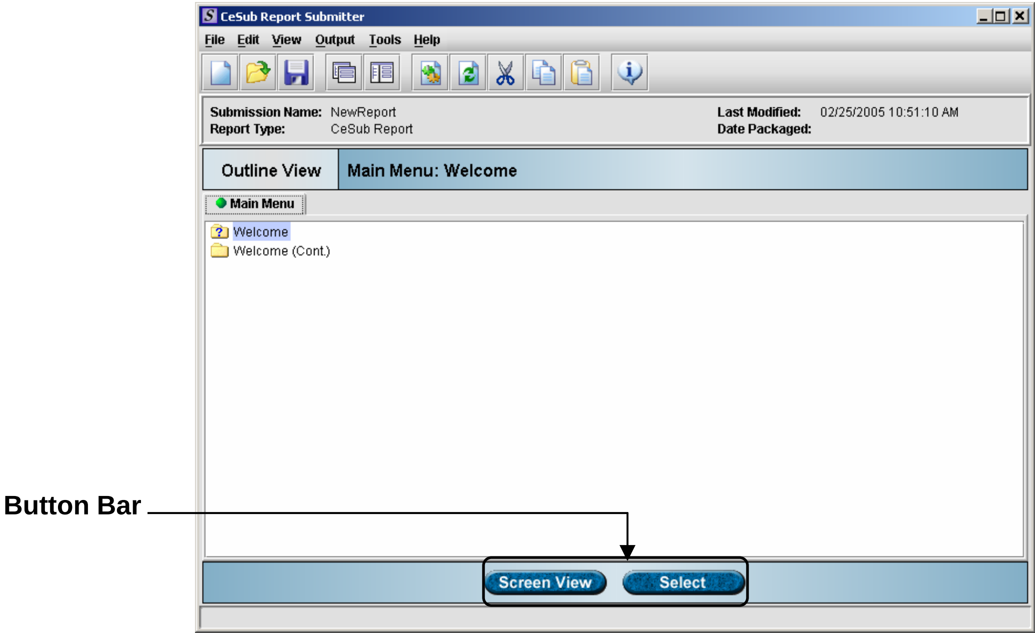


Figure 16: Simple Layout, Outline View

- **Expert** layout **–** Displays the overall report outline and current data entry screen side-by-side. This layout is most useful when additional display area is available. It also simplifies non-sequential movement through the report, such as updating various sections after the initial data entry is complete. *Figure 17* shows an Expert Layout.

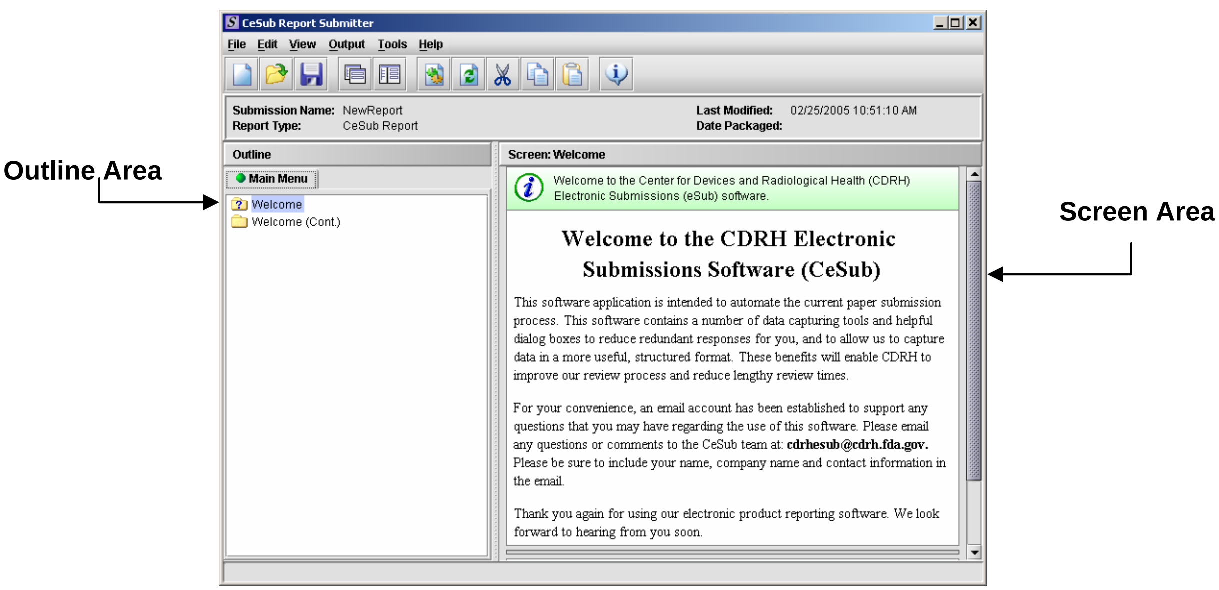
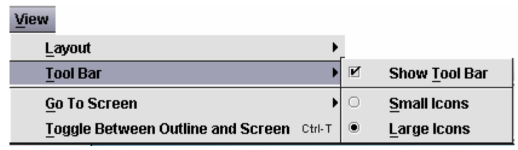
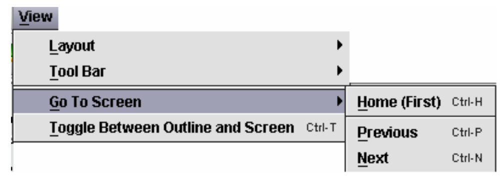


Figure 17: Expert Layout

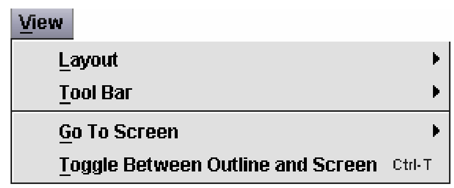
Tool Bar – Provides options for hiding and showing the tool bar, as well as, changing the sizes of the images within the tool bar buttons (i.e., small or large images).



Go To Screen – Provides options for moving directly to the first screen within the report, as well as the previous or next screen. Keyboard short-cuts for these options are also provided.

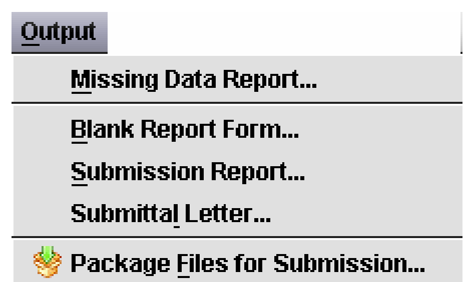


Toggle Between Outline and Screen – Switches the focus between the outline and the screen. Since there is a keyboard short-cut, this feature is most useful when attempting to quickly switch between the interface outline area and the screen area when using only the keyboard. This command is used with the Simple layout.



4.2.4 Menu Bar - Output

The **Output** menu includes commands related to the output of reports for submission information. For complete information on getting a submission ready to send to CDRH, see *Completing a Submission*, beginning on page 67.



Note: All report outputs are generated as HTML and require an application capable of viewing HTML output, such as a WEB browser, the full version of Adobe Acrobat (not Acrobat Reader), or Microsoft Word. When you select an item from the **Output** menu you will see a **Report Output Dialog** box, which allows you to select your HTML viewer. For additional information on the **Report Output Dialog** box and printing report outputs, see page 72.

Each command on the **Output** menu is described below:

Missing Data – Provides a list of required questions that you have not yet answered. The list is provided in HTML format. You can save the report file at any time. However, you will not be able to create a submission file to submit to CDRH until there is no missing data. For complete information, see *Completing a Submission*, beginning on page 67.

Blank Report Form – Views/prints a blank submission form in HTML.

Submission Report – Views/prints out the submission report with your entries in HTML.

Submittal Letter – Provides a formatted cover letter in HTML for you to sign that identifies your file and must be submitted along with the CD and any hardcopy of the report (if required) to CDRH.

Package Files for Submission – Displays the **Package Files for Submission Dialog** box, which creates all the files that are required for submitting a submission report to CDRH. However, the submission data files will only be generated when no required data is missing from the report. For complete information on packaging files for a submission, see *Completing a Submission*, beginning on page 67.

4.2.5 Menu Bar - Tools

Each command on the Tools menu is described below:

Establishment Address Book – Displays the **Establishment List Dialog** box, which provides the ability to maintain the addresses of the pertinent manufacturing and corporate facilities associated with your reports.

You only need to enter each company name and address once into the Establishment Address Book, then select the appropriate entry in response to each question. If the mailing address is the same as the physical address, the physical address can be copied into the mailing address fields. If they are similar but not exactly the same, it can be copied, and then edited. The Establishment Address Book will always be accessible for future reports, and you can update it as needed. This should reduce confusing, misspelled, and redundant entries. *Figure 18* shows an example of an **Establishment List Dialog** box containing an entry for an establishment.

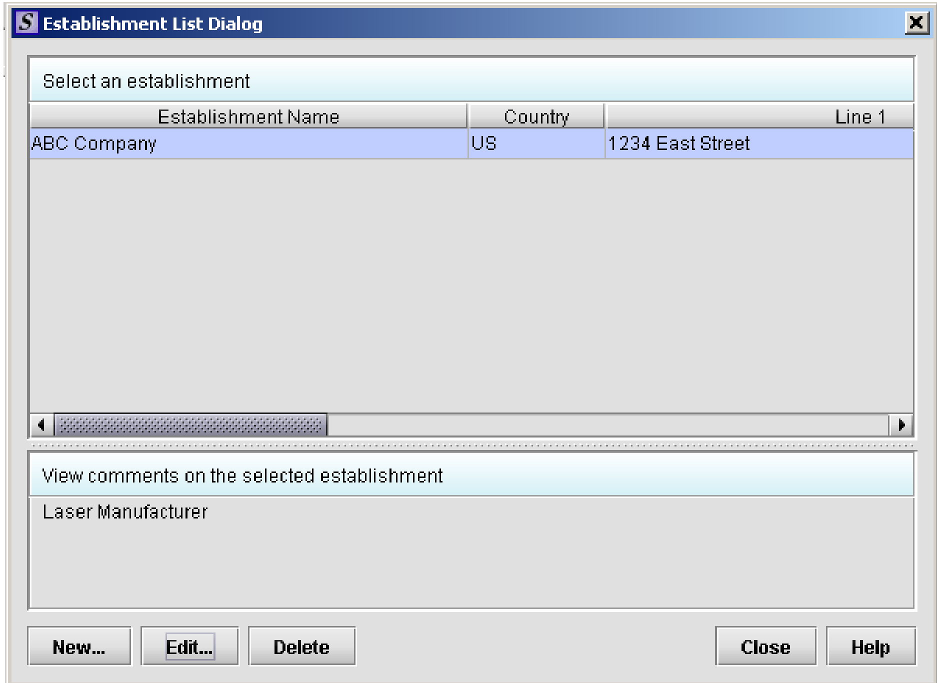


Figure 18: Establishment List Dialog Box

The **Establishment List Dialog** box contains a list of all the available establishments and a comments area for viewing the comments on the selected establishment. In addition, if you scroll across the establishment list, you'll see fields containing basic identifier information about each establishment.

The options (**New**, **Edit**, **Delete**, **Close**, and **Help**) in this dialog box are described below:

- **New –** Displays the **New Establishment dialog** which allows a new establishment to be created. *Figure 19* shows an example of this dialog box. Enter information in the fields to identify a particular establishment.

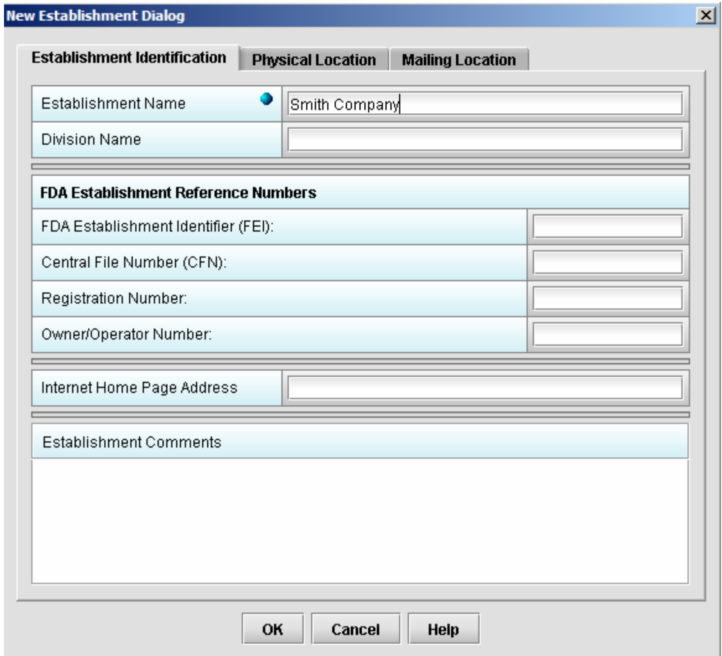


Figure 19: New Establishment List Dialog Box

To enter address information:

⇒ Click the **Physical Location** tab to enter address information for where the establishment is physically located. See *Figure 20*.

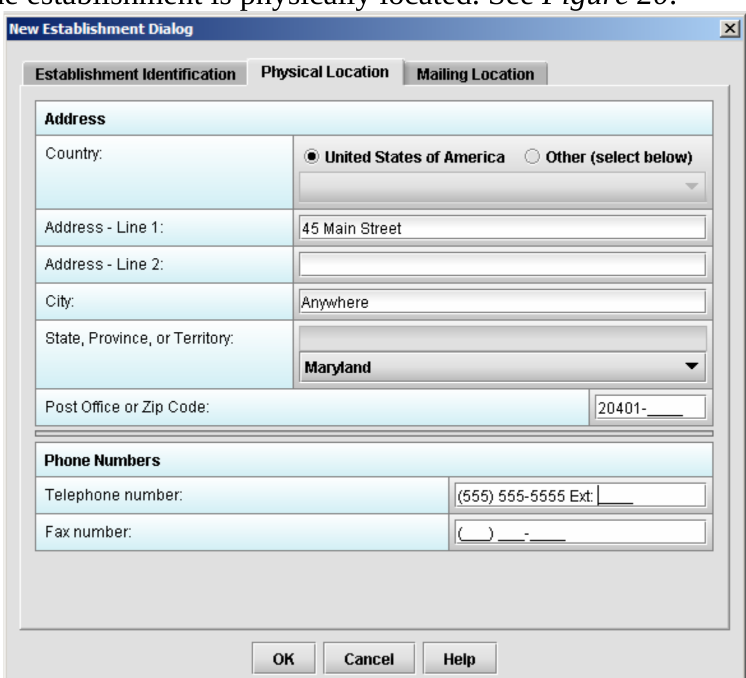


Figure 20: Editing the Physical Location Tab

⇒ Click the **Mailing Location** tab to enter address information for the mailing address of the establishment. See *Figure 21*.

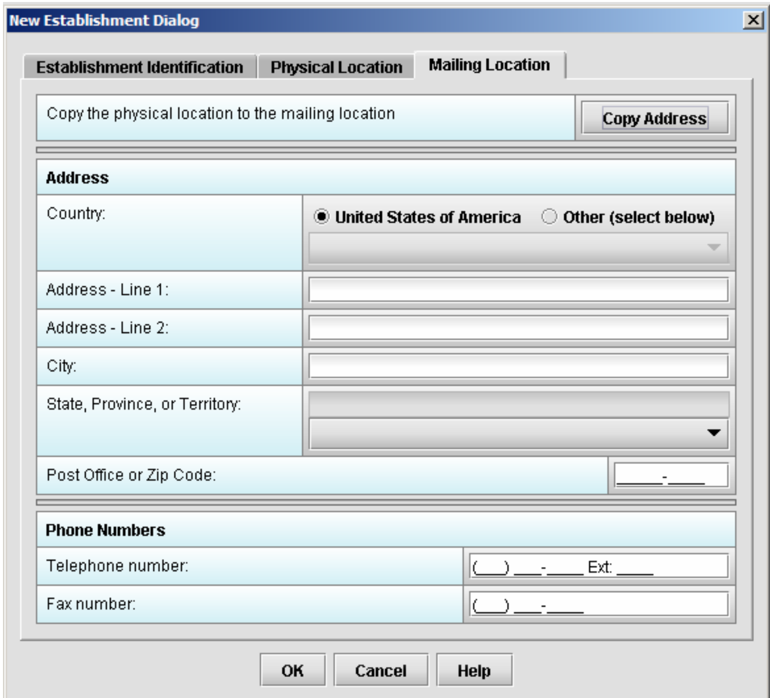


Figure 21: Editing the Mailing Location Tab

⇒ Click **Copy Address** if the mailing address is the same as the physical location of the establishment. The information is automatically copied into the address fields. See Figure 22 for an example.

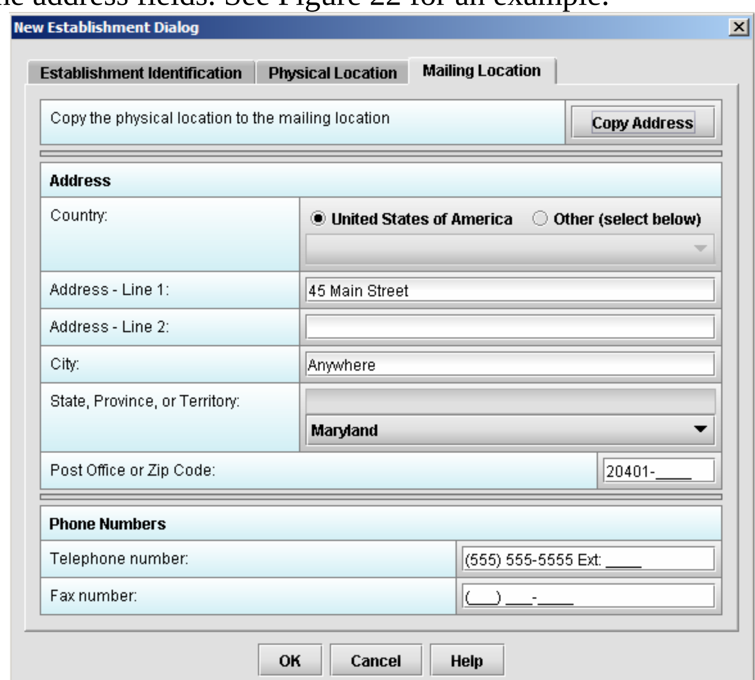


Figure 22: Copying the Mailing Location Tab

⇒ When you are finished with the addresses, click **OK** to save your edits, **Cancel** to ignore all edits, or **Help** to see help text. You return to the **Establishment List Dialog** box.

- **Edit –** Displays the **Edit Establishment Dialog** box which allows the selected establishment information to be changed. (You enter information in this dialog box in the same manner as the **New Establishment Dialog** box.)

- **Delete –** Deletes the selected establishment from the list.

- **Close –** Closes the dialog box.

- **Help –** Displays the help window with help text.

Contact Address Book – Displays the **Contact List Dialog** box, which allows the names and addresses of the pertinent people associated with the report to be maintained. You need only to enter each person's name and contact information once into the Contacts Address Book, and then you can select the appropriate individual in response to each question. Existing Establishment addresses can be selected (from the Establishment Address Book) for each contact. The Contact Address Book will be retained and accessible for future reports, and you can update it as needed. This should reduce confusing, misspelled, and redundant entries.

The **Contact List Dialog** box contains a list of all the available contacts and a comments area for viewing the comments on the selected contact. In addition, if you scroll across the contact list, you will see fields containing basic identifier information about each contact. *Figure 23* shows an example of a **Contact List Dialog** box containing entries for contacts.

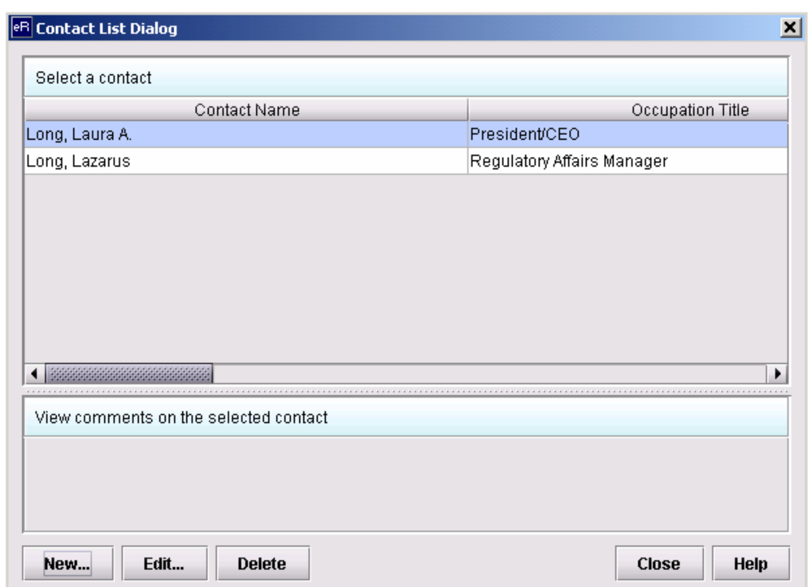


Figure 23: Contact List Dialog Box

The options provided in this dialog box are described below:

- **New –** Displays the **New Contact Dialog** box, which allows a new contact to be created.

- **Edit –** Displays the **Edit Contact Dialog** box, which allows the selected contact information to be changed.

- **Delete –** Deletes the selected contact from the list.

- **Close –** Closes the dialog box.

- **Help –** Displays the help window with this help text

Submission File List – Displays the **File List Dialog** box, which allows attached file information to be entered once for a submission but reused across questions in the report. For complete information on preparing a submission, see page 43. File attachments must be in PDF.

Attaching PDF files requires software capable of viewing and/or printing PDF files (e.g., Adobe Acrobat). The first time a PDF file is attached, the software will prompt you to locate the application within the system that will be used to view/print such files. (See *Figure 24*.) Once identified, the software will no longer prompt for this information. For information on setting up your PDF Viewer, see page 13.

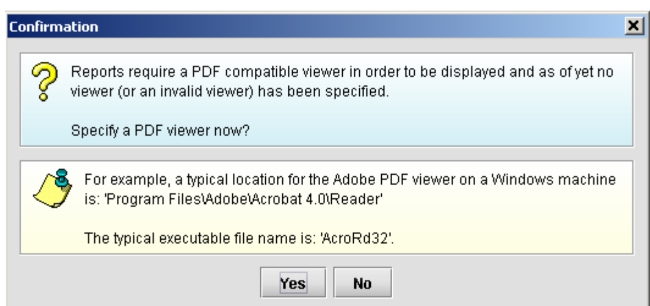


Figure 24: Confirmation Dialog Box

<u>Note:</u> The file list is specific to the report that is currently open.

The **File List Dialog** box manages the file attachment information related to the open report. The dialog box contains a list of all the attached files that are currently available, an area for general information on the selected file, and options for managing the list. The file list displays the following for each:

- Descriptive title
- Physical file name
- Number of questions that currently reference the file as an attachment
- File date

- File size
- Path to the file location

Figure 25 shows an example of a **File List Dialog** box with an attachment listed.

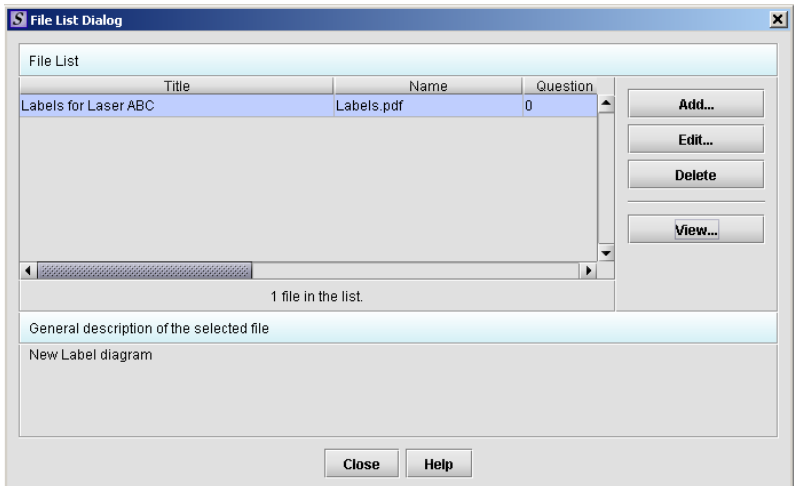


Figure 25: File List Dialog Box

The options provided in the dialog box are described below:

- **Add –** Displays the **New File Dialog** box, which allows a new file to be added to the list of attachments.

- **Edit –** Displays the **Edit File Dialog** box, which allows the selected file title and general description to be changed.

- **Delete –** Deletes the selected file from the list.

- **View –** Displays the selected file within the specified PDF viewer.

- **Close –** Closes the dialog box.

- **Help –** Displays the help window with this help text.

Assign Report ID– Allows you to enter an FDA-related identifier to a submission. After you have sent the submission to the FDA for processing and have received an acknowledgement, you can record the unique identifier assigned by CDRH (such as an accession number). For complete information on preparing a submission, see page 43.

To enter a Report ID:

⇒ Select **Assign Report ID** from Tools on the Menu bar. You see the Assign Report ID dialog box as shown in *Figure 26*.

⇒ Enter the unique identifier assigned by CDRH.

⇒ If you are satisfied with your entry, click **OK**. Or, click **Cancel** to close the dialog box without making any changes.

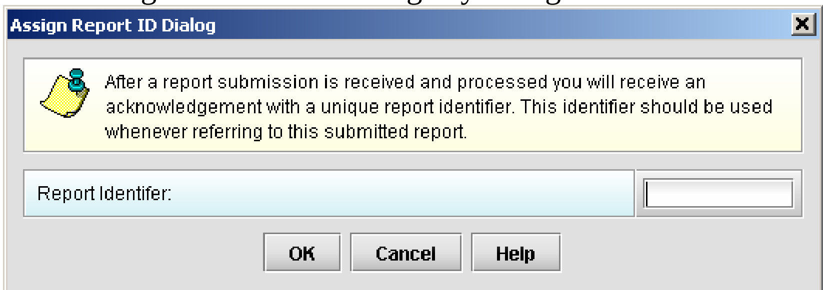
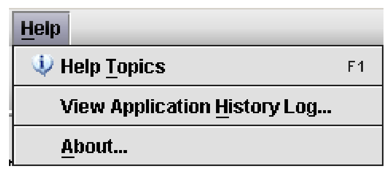


Figure 26: Assign Report ID Dialog Box

4.2.6 Menu Bar - Help



The **Help** menu provides access to help information: **Help Topics**, **View Application History Log**, and **About**.

Help Topics – Displays the Help window. The window contains a tool bar, outline area, screen area, and a splitter bar, which are described as follows and shown in *Figure 27*:

- **Tool Bar** - The tool bar provides options to move back and forth between topics (similar to the history in a browser, the back and forth buttons move between topics in the order they were viewed, not the order they appear within the outline), print the screen area, and set up the printer.
- **Outline Area** - The outline area contains a table of contents that lists the help topics.
- **Screen Area** - The screen area displays the help contents for the section selected in the table of contents.
- **Splitter Bar** - The splitter is the vertical bar between the outline and screen areas. By dragging the bar with the mouse left or right, you can control the proportion of the window that is allocated to each of the areas. Each menu item within the Help menu is identified and described on the next page:

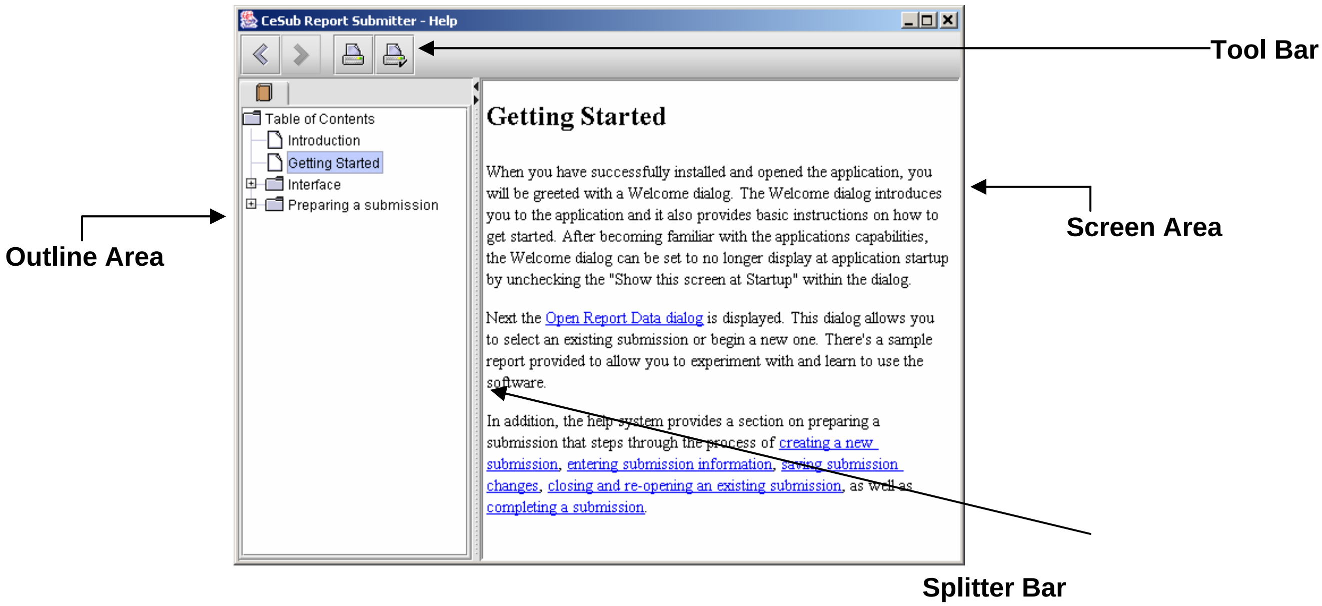


Figure 27: Help Window

View Application History Log – Displays the **View Application History/Updates Dialog** box which provides a history of changes to eSubmitter software. Changes are listed in reverse chronological order by version number. See *Figure 28.*

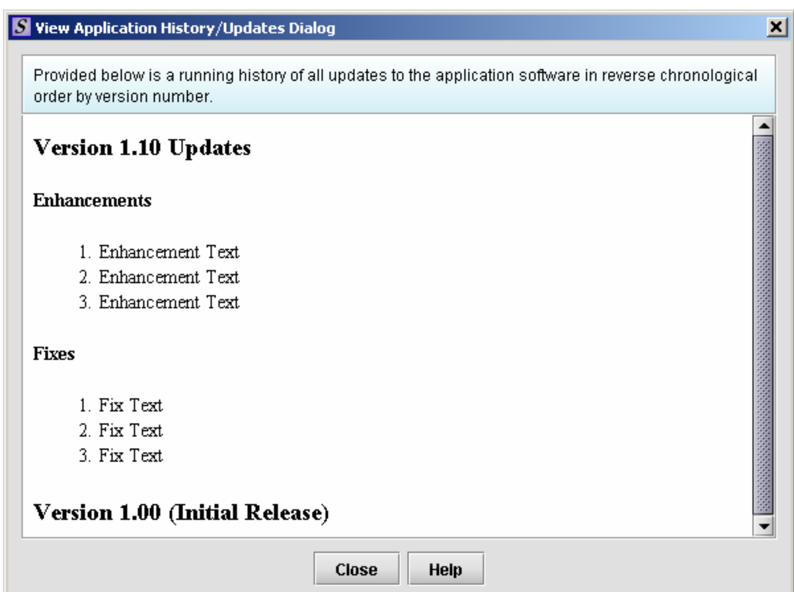


Figure 28: View Application History/Updates Dialog Box

About – Displays the **About** dialog box which provides general information about the application. See *Figure 29.*

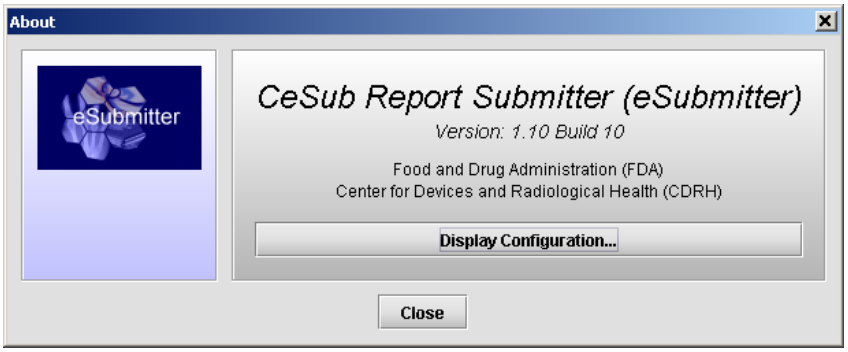


Figure 29: CeSub About Dialog Box

4.3 TOOL BAR

The tool bar (*Figure 30*) is a row of buttons that are designed to provide quick access to specific or commonly used commands and options. The tool bar is located below the menu bar. The buttons on the tool bar are grouped by functionality and are described below:

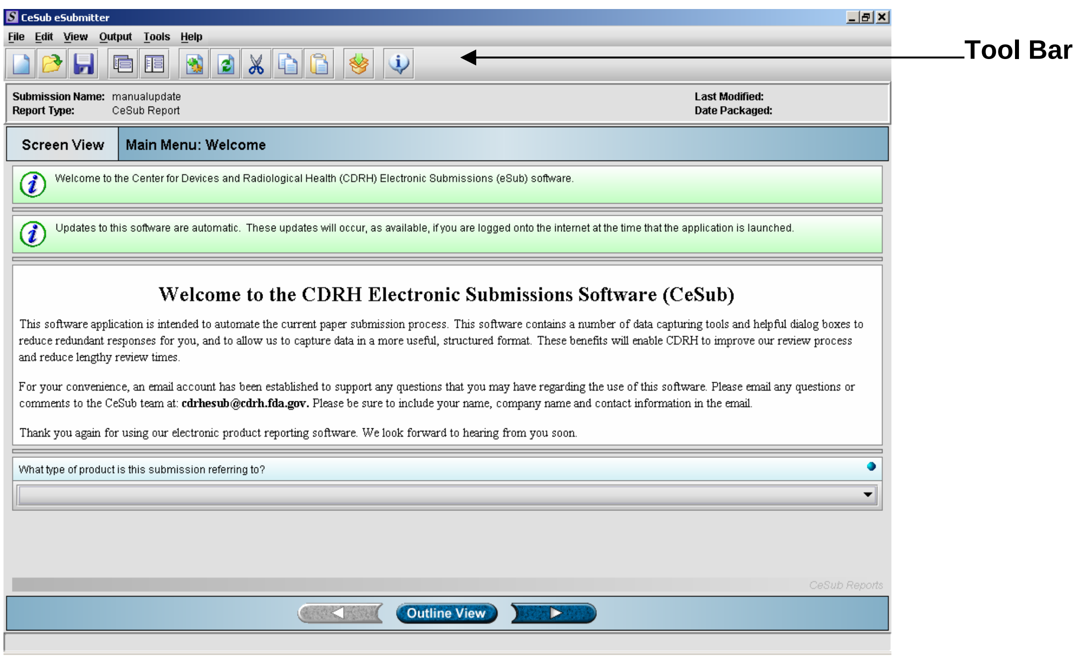
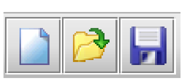


Figure 30: Tool Bar

File Options



- **New** - Displays the New Submission dialog which allows a new (empty) submission to be created.

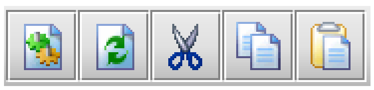
- **Open** - Displays the Open Submission dialog which allows an existing submission to be selected and opened.

- **Save** - Saves any changes within the open submission to permanent storage (e.g., to the disk)

Layout Options 

- **Simple –** Selects the simple layout, which displays the current data entry screen and contains basic options for moving forward/backward through the report one screen at a time.

- **Expert –** Selects the expert layout, which contains the overall report outline and current data entry screen side-by-side.

Edit Options 

- **Process Screen Changes** - Processes your changes to screens without saving the report or selecting another node. This option allows you to see your changes quickly.

- **Screen Undo** - Refreshes the data in all the data entries displayed within the screen area (the area to the right of the report outline) with their initial values before any changes were made.

- **Cut -** Removes the selected text from within the data entry area that currently has the focus and transfers it to the system clipboard.

- **Copy** - Copies the selected text from within the data entry area that currently has the focus and transfers it to the system clipboard.

- **Paste** - Pastes the text from the system clipboard into the data entry area that currently has the focus.

Package Files for Submission 

- Allows you to package your submission to send to CDRH after you have completely answered all questions, and no data is missing. For complete information, see *Packaging Submission Files* on page 70.

Help Options 

- **Help** - Displays the **Help** window and help topics.

4.4 PRIMARY WORK AREA

The primary work area is the section of the application window that is located between the tool bar and the status bar. This area contains either the **General Screen** or the **Submission Display Screen**.

The **General Screen** is displayed when no submission is currently open and contains identification information about the application. See *Figure 31*.

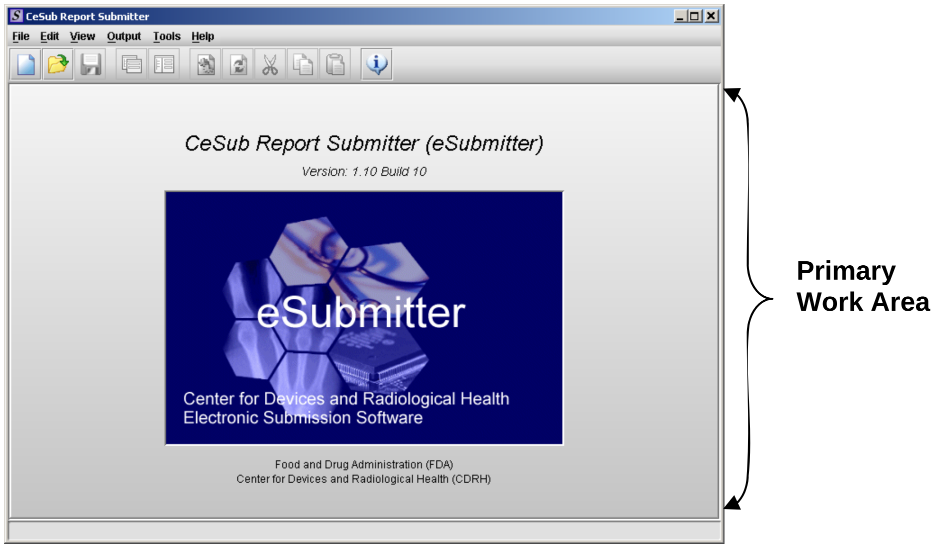


Figure 31: Primary Work Area in a General Screen

The **Submission Display Screen** is shown when a submission is currently open and contains identification information about the application. See *Figure 32*.

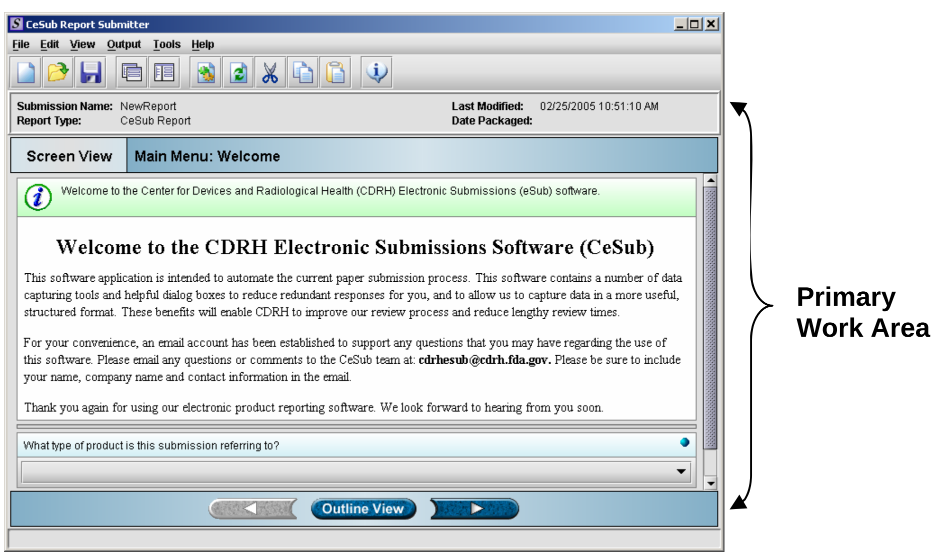


Figure 32: Primary Work Area in a Submission Display Screen

4.4.1 Layouts of a Primary Work Area in a Submission Display Screen

The Submission Display Screen is displayed in one of two layouts when a report is open.

Simple layout – separates the Submission Display Screen into three additional areas (as shown in *Figure 33*):

- **Header Area** (located at the top)
- **Outline Area** or **Screen Area** (located in the middle)
- **Button Bar** (located at the bottom), which allows forward and backward movement through the screens, as well as the ability to switch back and forth between the outline or screen view.

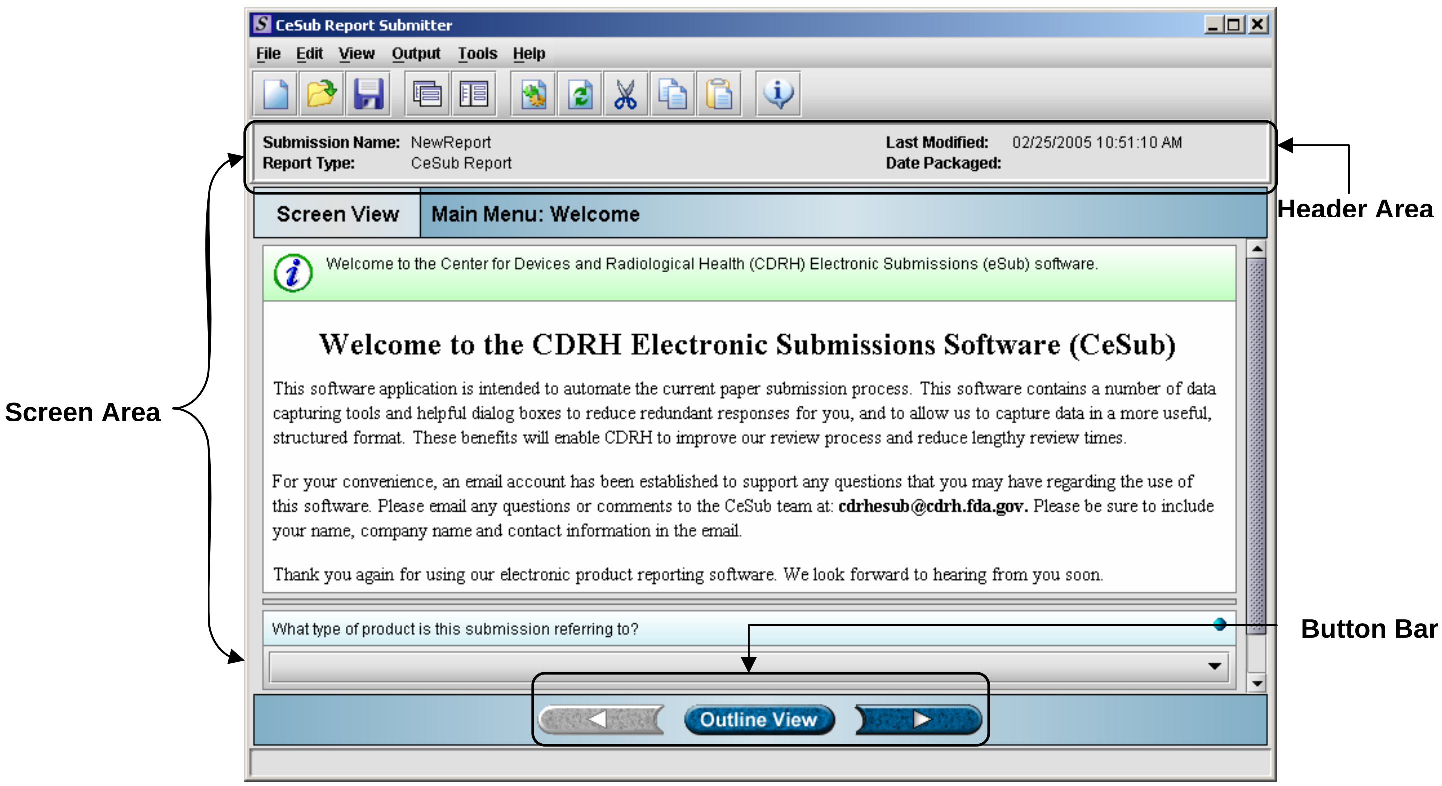


Figure 33: Primary Work Area, Simple Layout

Expert layout – separates the Submission Display Screen into four additional areas (as shown in *Figure 34*):

- **Header Area** (located at the top)
- **Outline Area** (located at the left)
- **Screen Area** (located to the right)
- **Splitter Bar** (located between the outline and screen areas)

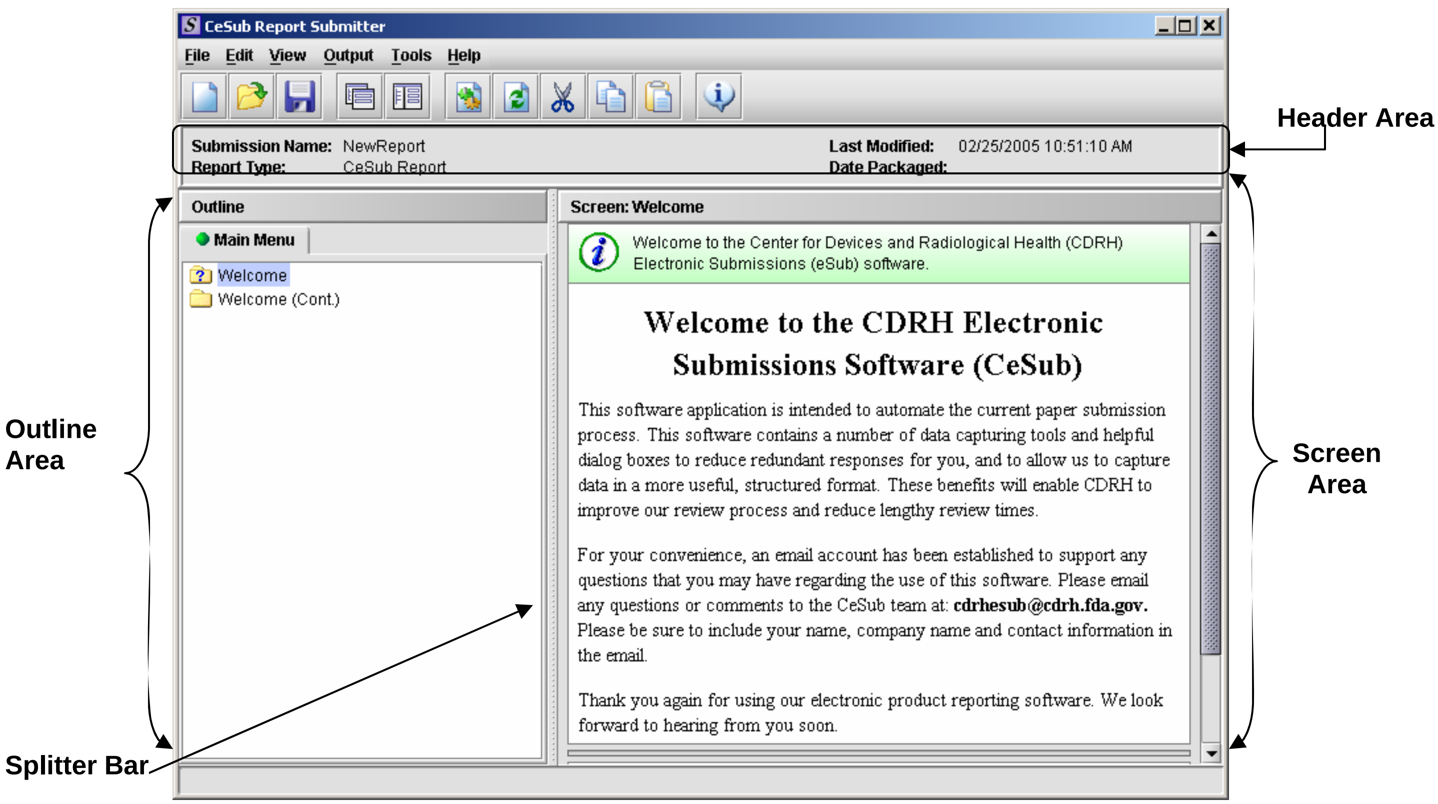


Figure 34: Primary Work Area, Expert Layout

4.4.2 Parts of the Primary Work Area

The different parts of the Primary Work Area are defined as follows:

Header Area – Displays the following general information about the open submission (see *Figure 33* and *Figure 34*):

- **Submission Name –** is the name that you created for the report.
- **Report Type –** will always be CeSub Report.
- **Last Modified** - represents the date and time the submission information was last saved to the disk file. The date and time are automatically updated after each save.
- **Packaged Date** - represents the date and time the submission files were generated for transfer to CDRH. The date and time are automatically set after the files are packaged for submission to CDRH.

Outline Area/View – Displays tabs that organize the report into sections (see *Figure 35* and *Figure 36*):

Each tab within the outline has an image to the left of its descriptive text. This image depicts which tab contains the section that is currently displayed within the screen area (i.e., the tab with the highlighted green image).

Each section within the outline contains a folder image to the left of the section text. This folder image depicts the status of required information that is missing from within the question responses of the section. For example:

- **Green check mark** indicates no required information is missing.
- **Blue question mark** indicates at least one item of required information is missing.
- **No mark** indicates that the section does not contain any required questions.

When in the Expert layout, activating a section within the outline area (by double-clicking or pressing the **Enter** key) will load the screen area to the right with the appropriate questions and responses associated with that section of the report. (See *Figure 35*.)

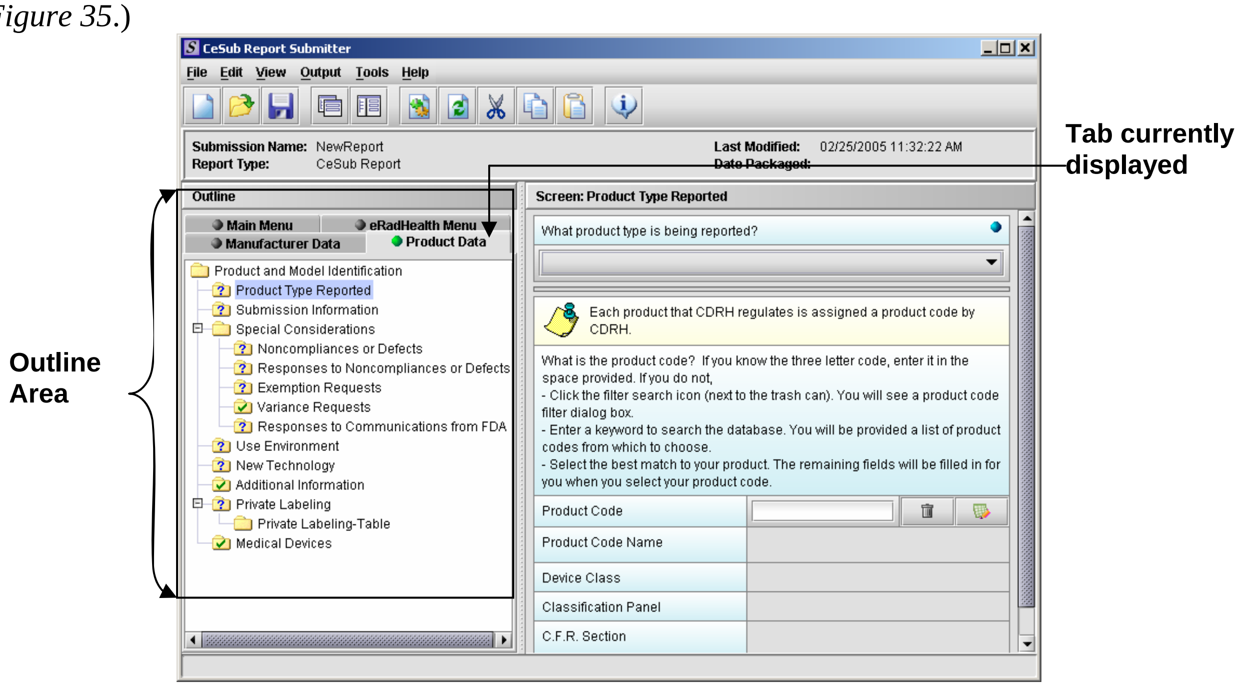


Figure 35: Outline Area in the Expert Layout

When in the Simple layout, activating a section within the outline view (by double-clicking a section or by selecting the section, then pressing the **Select** button) will load the screen view with appropriate questions and responses associated with that section of the report. See *Figure 36* for an example.

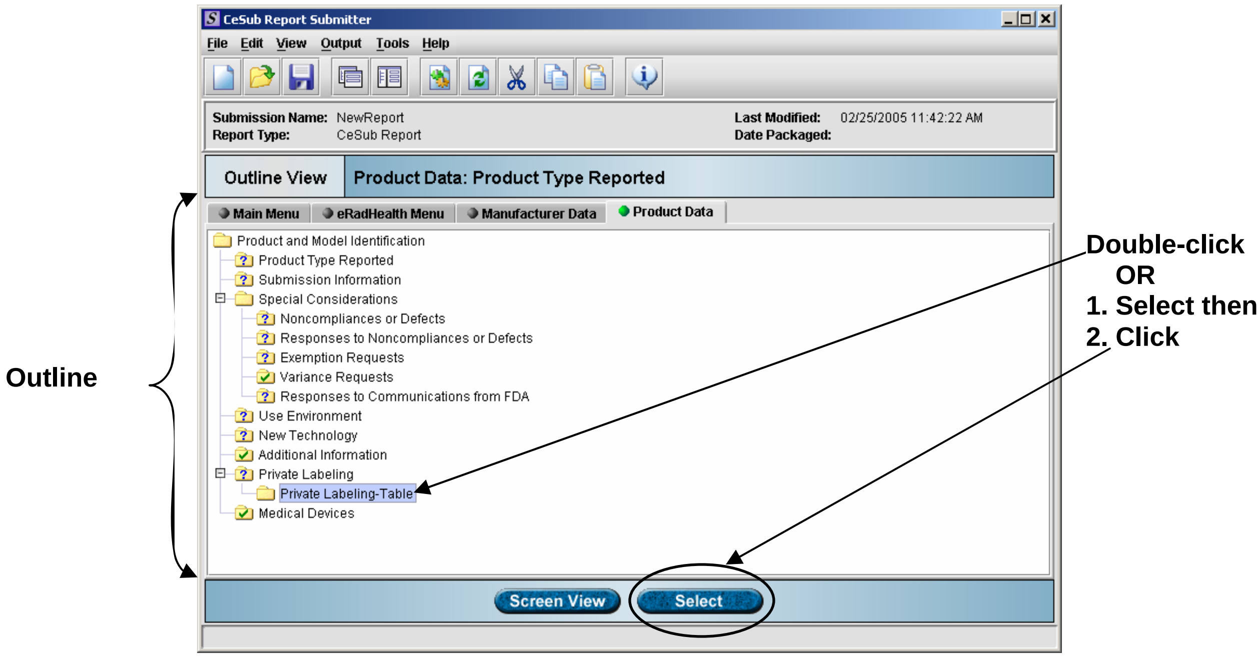


Figure 36: Outline View in the Simple Layout

Screen Area/View – displays the questions and responses associated with the selected section in the outline area. There is complete flexibility in maneuvering through the screen area. However, questions should be answered in order. Responses to some questions will determine whether further questions are required or even applicable, which means they may become disabled.

Some questions within the screen area may be required in order for the report to be considered complete. These questions are designated with a blue dot to the right of the question text. A complete list of required information that is currently missing from the report can be accessed by selecting the **Identify Missing Data** option on the **Output** menu. (For complete information about this option, see pages 24 and 67.)

See *Figure 37* and *Figure 38* for examples of screens in the Expert Layout and Simple Layout, respectively.

When in the Simple layout, you can click the arrow buttons (at the bottom of the window) to advance to the next screen in the report or return to the previous screen. Clicking the **Outline View** button will switch to the Outline View. See *Figure 38*.

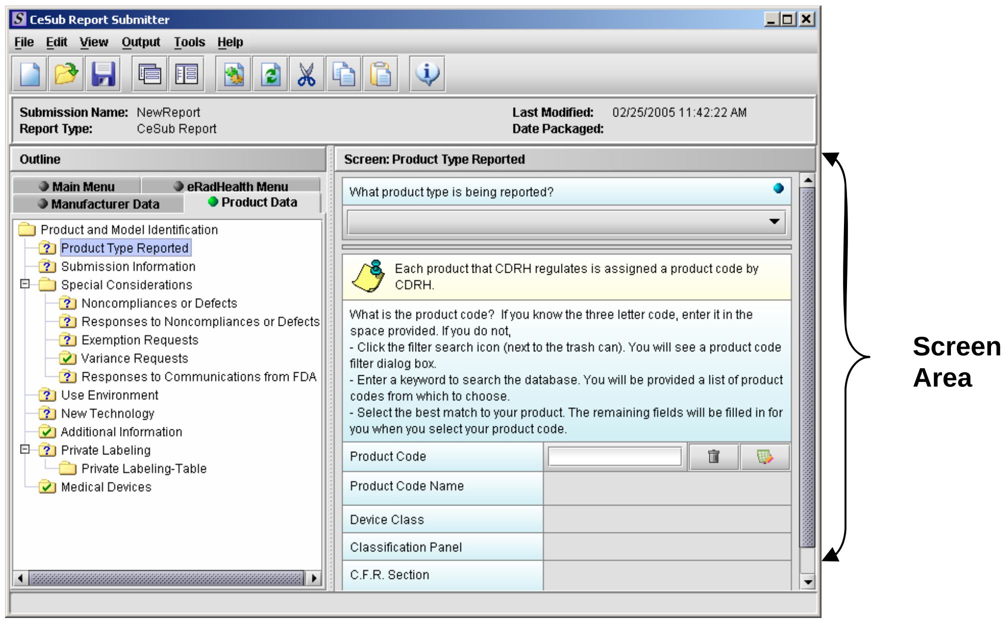


Figure 37: Screen Area in the Expert Layout

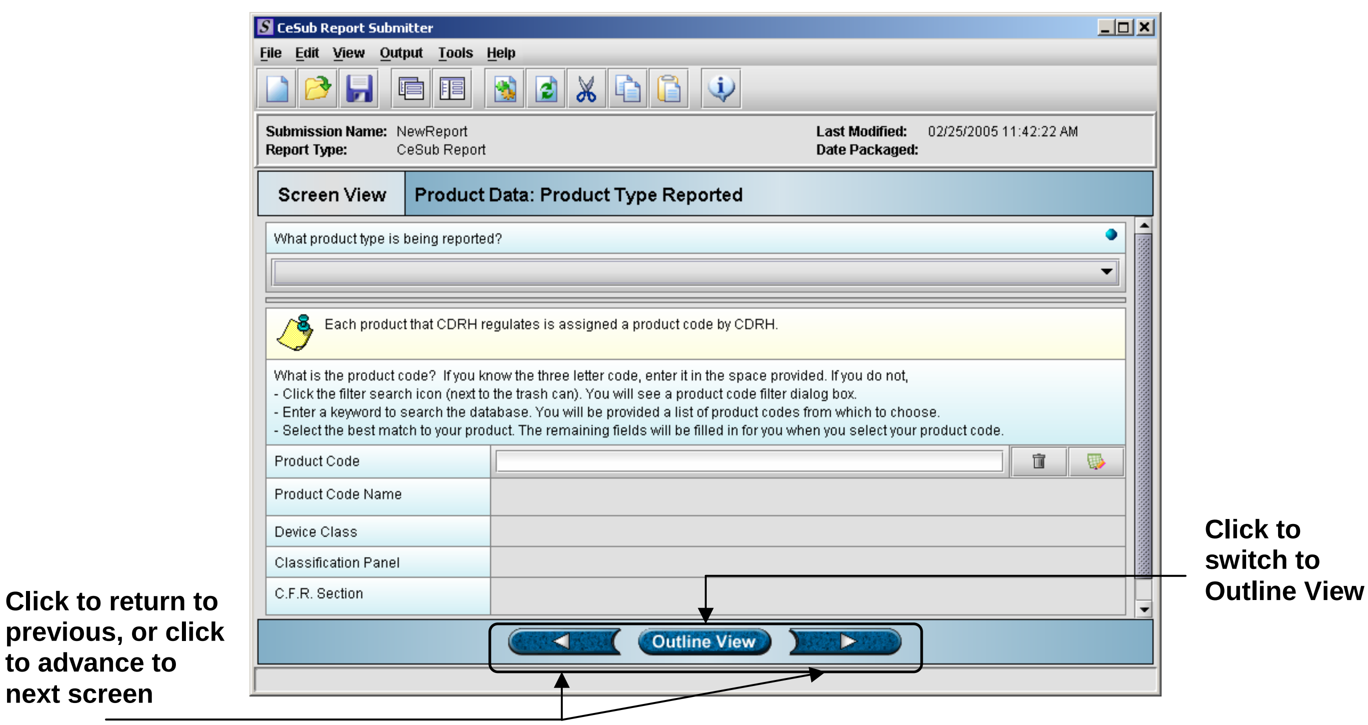


Figure 38: Screen View in the Simple Layout

Splitter Bar – Is the vertical bar between the outline and screens areas in the Expert layout, as shown in *Figure 39*. By dragging the bar with the mouse to the left or right you can control the proportion of the window that is allocated to each of the areas. Adjusting this bar may be necessary on smaller monitors in order to improve readability of the text. See *Figure 39*.

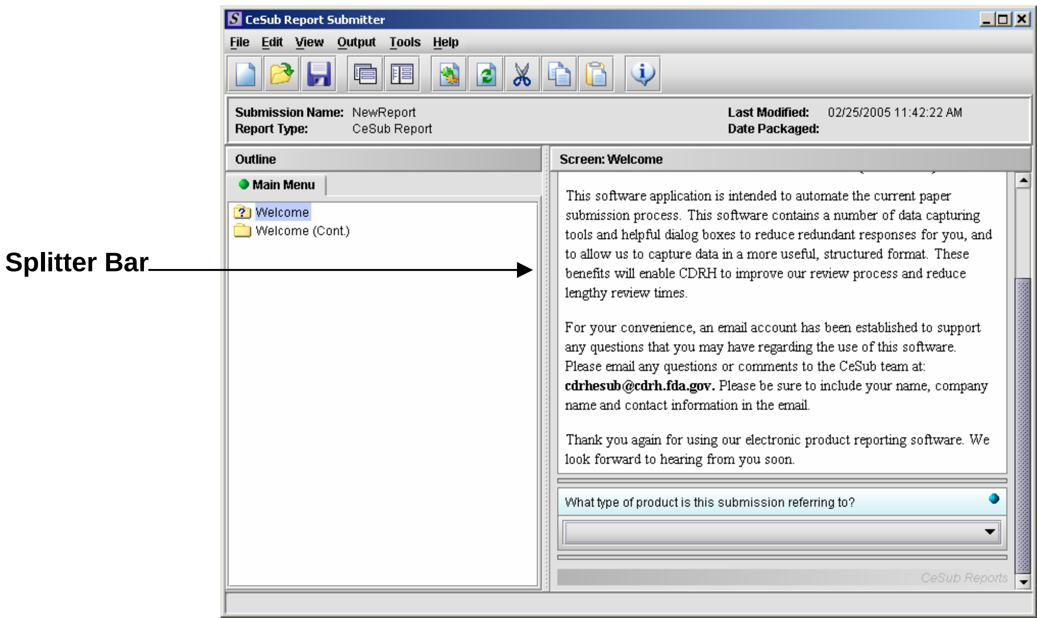


Figure 39: Splitter Bar Location

5. PREPARING A SUBMISSION

5.1 CREATING A NEW SUBMISSION

This section provides an overview of creating a new submission report.

Note: Before proceeding, make sure you have already reviewed the **Introduction**, **Getting Started**, and **Interface** sections of this user manual. These sections provide valuable information that is necessary in order to follow and understand the instructions in this section.

There are two methods for creating a new submission report: starting from scratch with a completely blank report or copying an existing report and making the required changes. The purpose for copying an existing report would be to save time because many of the responses are the same. This might be the case if you have an existing report from the same model family or you are submitting a report supplement. The steps involved for both of these methods are provided below.

To create a new blank submission report from scratch:

1. The CeSub eSubmitter application should be open on your computer desktop. If it is open, and you see the **General Screen**, go to step 2. If the application is not open:
   - Click **Start**, and select **Programs > CeSub Report Submitter > eSubmission**. You will see the **Welcome** dialog box (unless it is set to no longer display, see page 8).
   - When you are finished reading the **Welcome** dialog box, click **Close**. You see the **Open Report Data Dialog** box.
   - Click **New Report Data**.
   - Go to step 3.
2. Click **File > New**. (Or, click the New report icon on the Tool Bar.)
3. You see the **New Report Data Dialog** box. An example is shown in *Figure 40*. Complete the fields on this dialog box as follows:
   - **Report type** – The entry is CeSub Report. **Do not change this entry**. (Required Entry, as indicated by the blue dot.)
   - **Descriptive name** – Enter any descriptive name, as long as it is unique to the submission list and not blank. Use a name that distinctly identifies the report to you. (Required Entry, as indicated by the blue dot.)
   - **File name** – Enter a valid name for the submission data. Use alphanumeric characters. (Required Entry, as indicated by the blue dot.) **File names should not contain more than 250 characters. Do not use symbols when naming the files**. For example, do **not** use slashes (/) (\), tildes (~), asterisks (*), periods (.), brackets [ ], single quotation marks (‘), double quotation marks (“) or parentheses ( ).
   - **Provide additional comments**… – Enter any additional information about this report (Optional Entry).

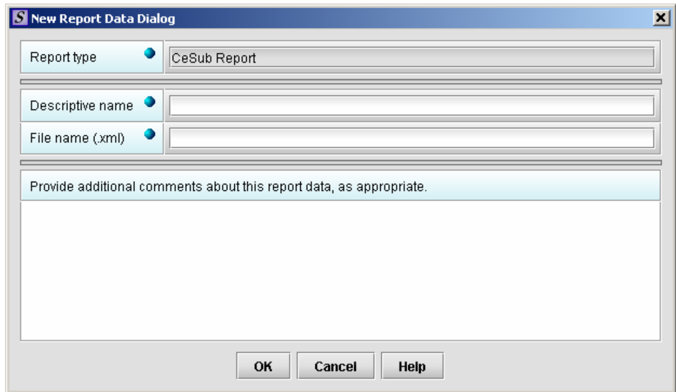


Figure 40: New Report Data Dialog Box

4. When you are finished entering all information in the fields, click **OK**.
   The first screen of your new blank submission report is displayed. See *Figure 44*.

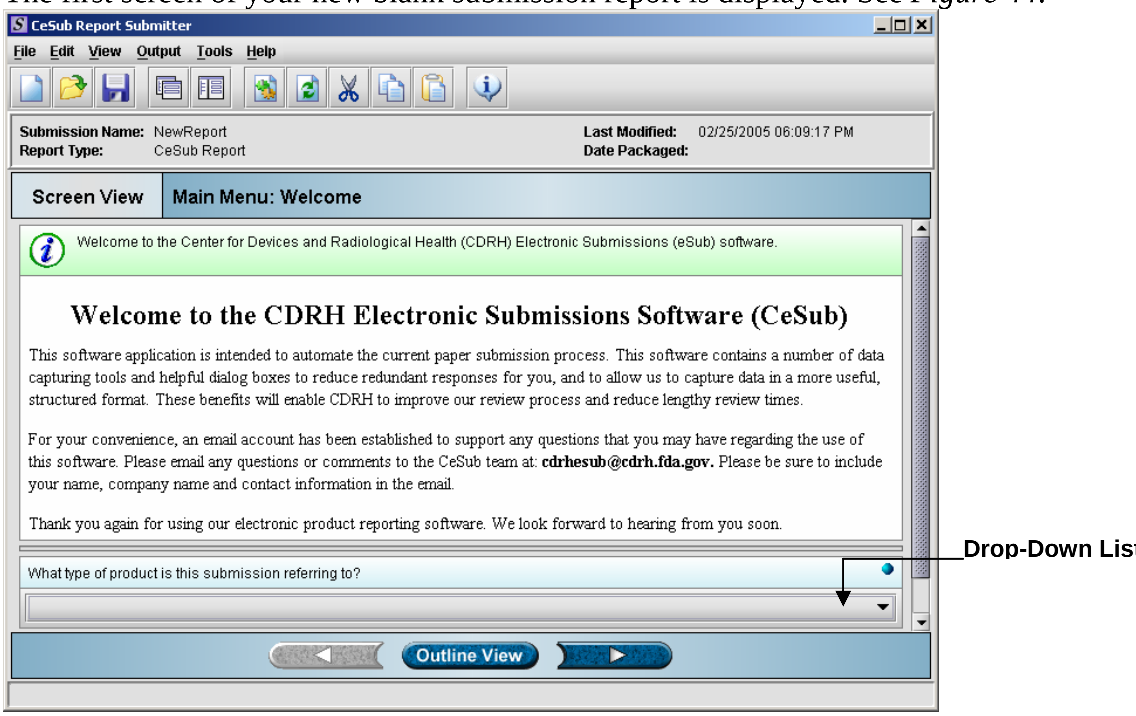


Figure 41: First Screen in a Report

5. On this screen:
   - Click the drop-down menu, and select one of the following: **In Vitro Diagnostic Device**, **Radiation Emitting Product**, or **Other**.
   - If you are in the simple layout (as shown in *Figure 44*), click next arrow button. If you are in the expert layout, click the **Welcome (Cont.)** node.
6. You are now ready to change the responses in this submission, go to *Entering Submission Information*, beginning on page 48.

To copy an existing report to create a new submission report:

1. The CeSub eSubmitter application should be open on your computer desktop.
   If it is open, and you see the **General Screen**, go to step 2. If the application is not open:
   - Click **Start**, and select **Programs > CeSub Report Submitter > eSubmission**.
     You will see the **Welcome** dialog box (unless it is set to no longer display, see page 8).
   - When you are finished reading the **Welcome** dialog box, click **Close**.
     You see the **Open Report Data Dialog** box.
   - Go to step 2.
2. Click **File > Open**. (Or, click the Open report icon  on the Tool Bar.)
3. You see the **Open Report Data Dialog** box, an example is shown in *Figure 42*.

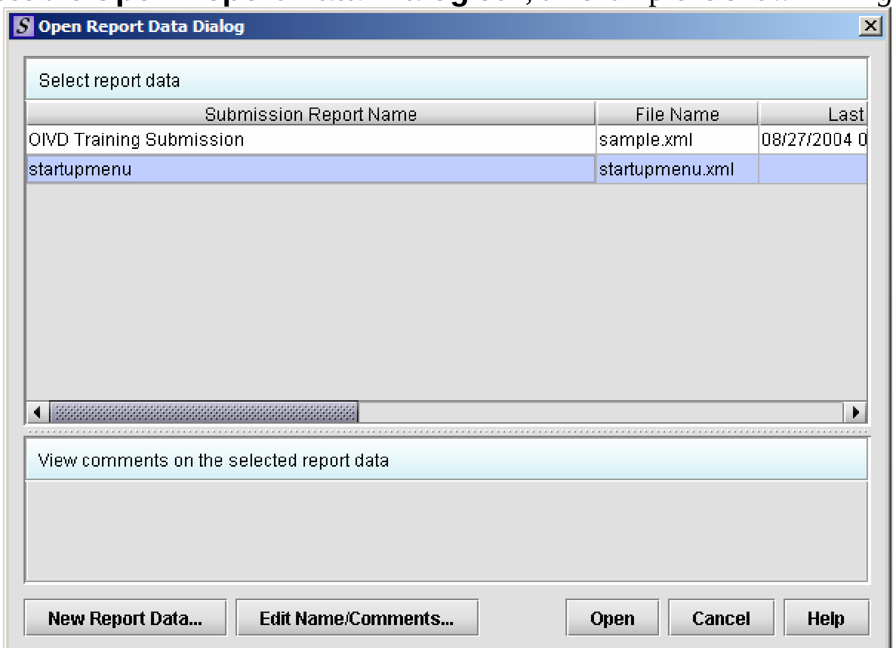


Figure 42: Open Report Data Dialog Box

   - Click to select the existing submission report to be used as a template, and click **Open**.
     The submission report is displayed on your computer.

4. Click **File > Save As**.

   You see the **Save Submission As Dialog** box. An example is shown in *Figure 43*.

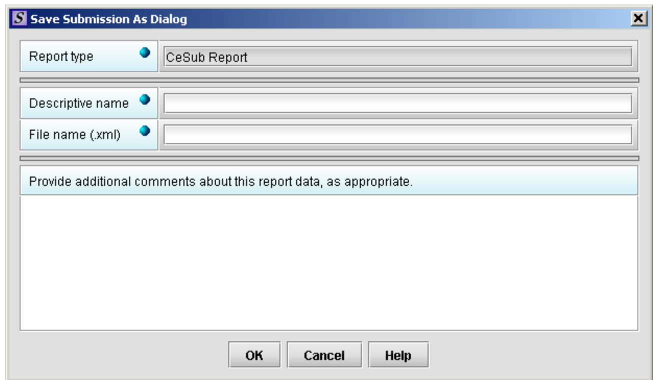


Figure 43: Save Submission As Dialog Box

5. Complete the fields on this dialog box as follows:
   - **Report type** – The entry is CeSub Report. **Do not change this entry.** (Required Entry, as indicated by the blue dot.)
   - **Descriptive name** – Enter any descriptive name, as long as it is unique to the submission list and not blank. Use a name that distinctly identifies the report to you. (Required Entry, as indicated by the blue dot.)
   - **File name** – Enter a valid name for the submission data. Use alphanumeric characters. (Required Entry, as indicated by the blue dot.)
   - **Provide additional comments**… – Enter any additional information about this report (Optional Entry).
6. When you are finished entering all information in the fields, click **OK**.
   The first screen of your new submission report is displayed. See *Figure 44*.

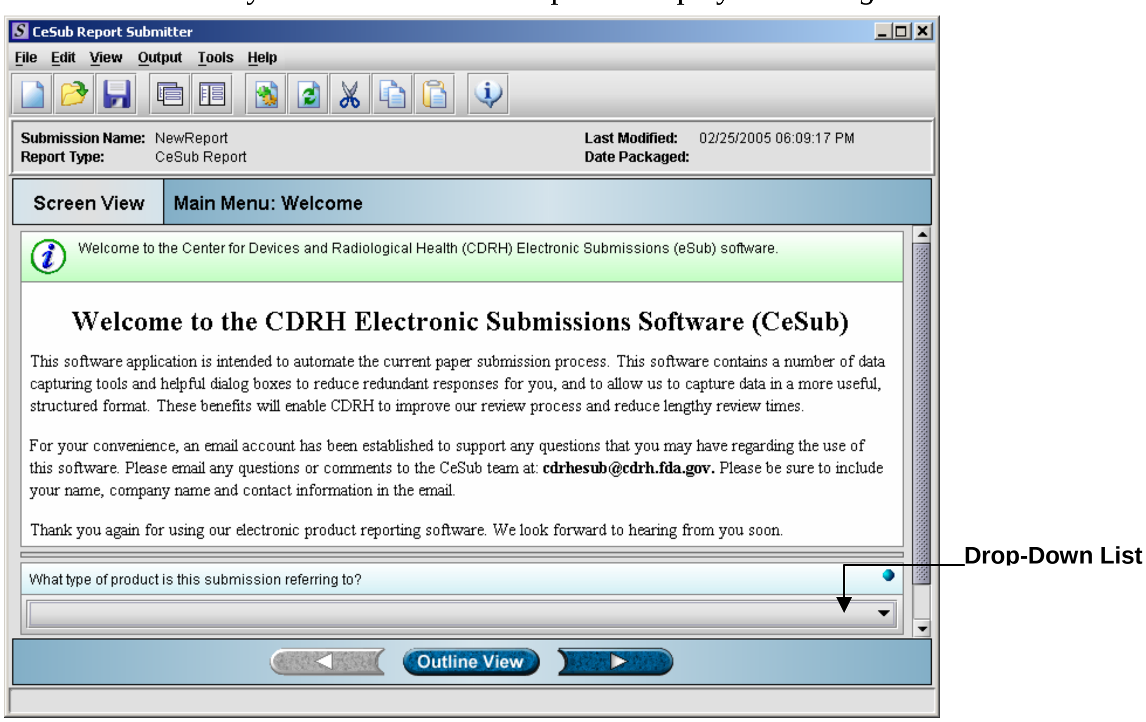


Figure 44: First Screen in a Report

7. Since you copied an existing submission, it already has many or all questions answered. You now have the opportunity to go through and change responses for this new submission. (Creating a new submission in this manner is handy if you are creating a supplemental report or creating a report for a product in an existing product family.) On this screen:
   - Click the drop-down menu, and select one of the following: **In Vitro Diagnostic Device**, **Radiation Emitting Product**, or **Other**.
   - If you are in the simple layout (as shown in *Figure 44*), click next arrow button. If you are in the expert layout, click the **Welcome (Cont.)** node.
8. You are now ready to change the responses in this submission, go to *Entering Submission Information*, beginning on page 48.

5.2 ENTERING SUBMISSION INFORMATION

Entering information for a submission requires stepping through the report and answering questions. If you use the simple layout, you progress through the report screen by screen, ensuring that you have filled in all appropriate responses. If you use the expert layout, you progress through the report outline sections, activate each section to load the section questions and responses, and ensure that you have filled in all appropriate responses. For additional information on the simple and expert layouts, see the *Primary Work Area*, beginning on page 36. You should follow the order of the sections as they are listed in the outline, the order has been set up to represent the most logical progression through the report.

5.2.1 Question Types

The CeSub eSubmitter application uses several different types of questions to capture all the information that is required for a specific report. The response that you enter depends on the type of question used in your particular report. For example, to answer a specific question, you may be required to select a response from a drop-down box, type in text, attach a separate PDF file, select a check box, or provide contact information.

This section describes each of the different question types and includes examples of their respective responses.

Note: **You may not see all of these types of questions in one particular report.** The purpose of this section is to provide a brief overview of all of the different question types that are used in the eSubmitter software.

Address – This question type requires that you enter the address and phone numbers of your establishment. You enter the information in text boxes and make selections using drop-down menus and clicking option buttons. An example is shown in *Figure 45.* Other types of address questions are **Establishment** and **Contact**. See pages 50 and 51, respectively.

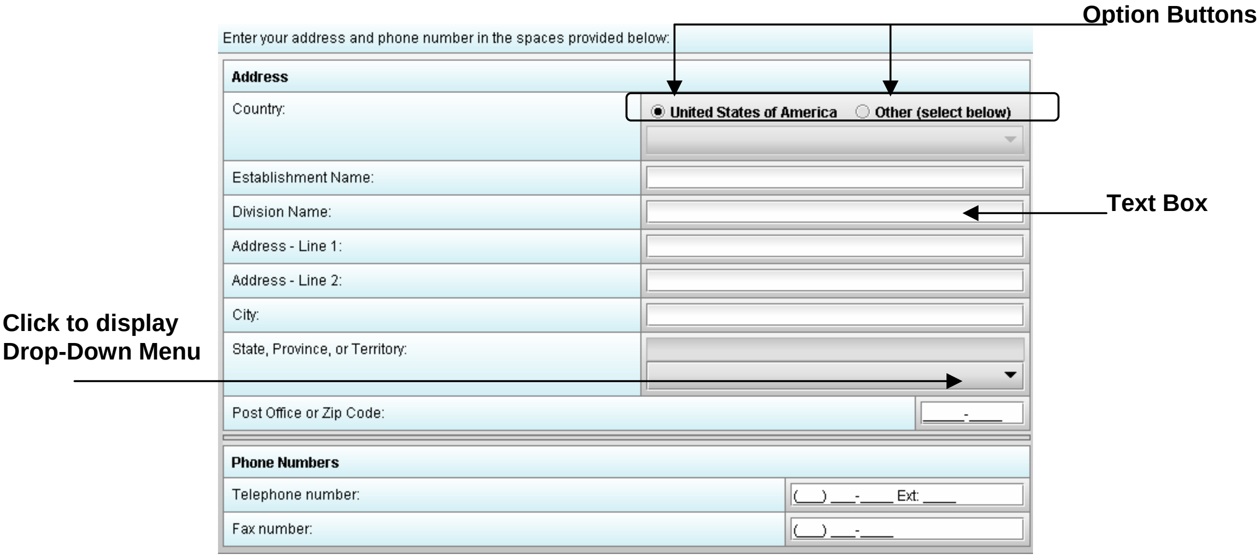


Figure 45: Example of an Address Question

Check Box – This question type requires that you click on the box to select or clear the check mark to answer a question. See the example in *Figure 46*.

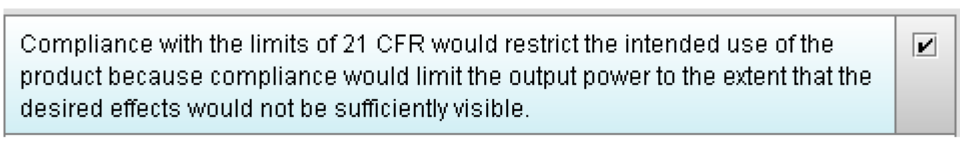


Figure 46: Example of Question with a Check Box

Contact (Simple) – This question type requires that you type contact information (first name, last name, etc.) in text boxes. Entries may or may not be required. *Figure 47* shows an example of a simple contact question with the first name and last name as required entries (as indicated by the blue dots). Entries in a simple contact question are saved with a specific submission but will not be captured in the Establishment or Contact Address Book. (See descriptions of Establishment and Contact questions on pages 50 and 51, respectively). For more information about Establishment Address Books, see page 25.)

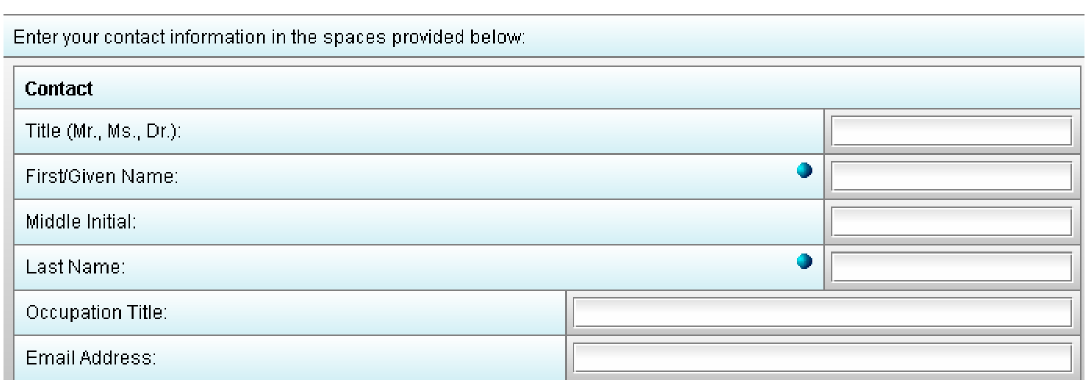


Figure 47: Example of a Simple Contact Question

Contact (Multi-Part) – This question types contains various areas that you need to complete (indicated by the tabs: Establishment Identification, Physical Location, and Mailing Location). For this question type, you may enter contact information (first name, last name, etc.) directly into text boxes, or you may copy this information from the Contact Address Book. When you enter the information directly (without using the Contact Address Book), the contact information is only saved for the submission. Copying the information from the Contact Address Book saves time for data entry because the information is automatically copied into the question. Information in the Establishment and Contact Address Books requires that you only enter the data once and reuse it across multiple submissions.
Figure 48 shows an example of a multi-part contact question.

To copy information from the Contact Address Book into the contact question:
1. Click the **Copy** button in the question.
2. Click to highlight and select the desired contact.
3. Click **Select**. The contact information is automatically populated in the different entry areas.
4. If the information is not exactly the same, you can edit the information after you have copied it.
5. To see the other information, click the desired tab. If you copied the contact information from the Contact Address Book, the information for these tabs will be completed as well.

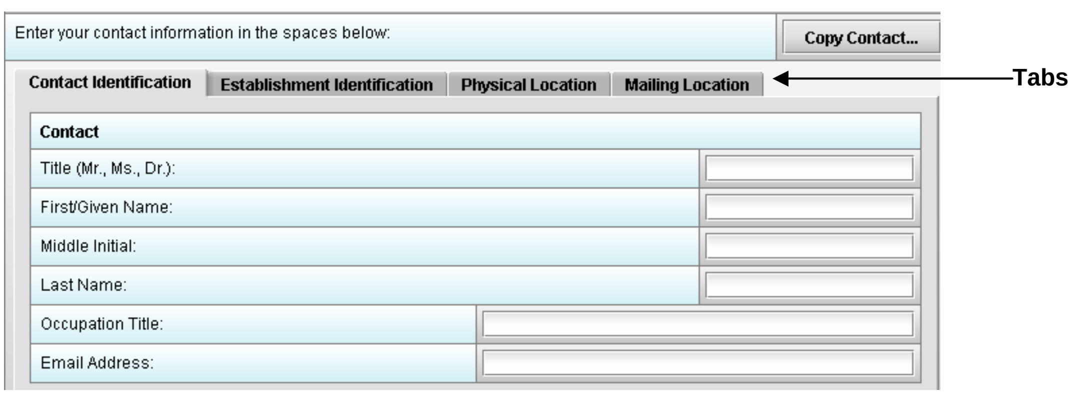


Figure 48: Example of a Multi-Part Contact Question

(See a description of an establishment question on page 51. For more information about Establishment Address Books, see page 25.)

Drop-Down Menu – This question types requires that you select a response from a list of entries that appear after you click the box with the down arrow (▼). *Figure 49* shows an example of a question with a drop-down menu.

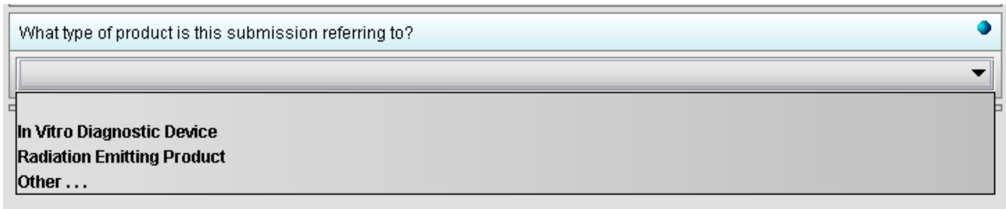


Figure 49: Example of Question with a Drop-Down Menu

Establishment – This question types contains various areas that you need to complete (indicated by the tabs: Physical Location and Mailing Location). For this question type, you may enter contact information (establishment name, etc.) directly into text boxes, or you may copy this information from the Establishment Address Book. When you enter the information directly (without using the Establishment Address Book), the establishment information is only saved for the submission. Copying the information from the Address Book saves time for data entry because the information is automatically copied into the question. Information in the Establishment and Contact Address Books requires that you only enter the data once and reuse it across multiple submissions. *Figure 50* shows an example of an establishment question.

To copy information from the Establishment Address Book into the establishment question:

1. Click the **Copy** button in the question.
2. Click to highlight and select the desired contact.
3. Click **Select**. The contact information is automatically populated in the different entry areas.
4. If the information is not exactly the same, you can edit the information after you have copied it.
5. To see the other information, click the desired tab. If you copied the contact information from the Contact Address Book, the information for these tabs will be completed as well.

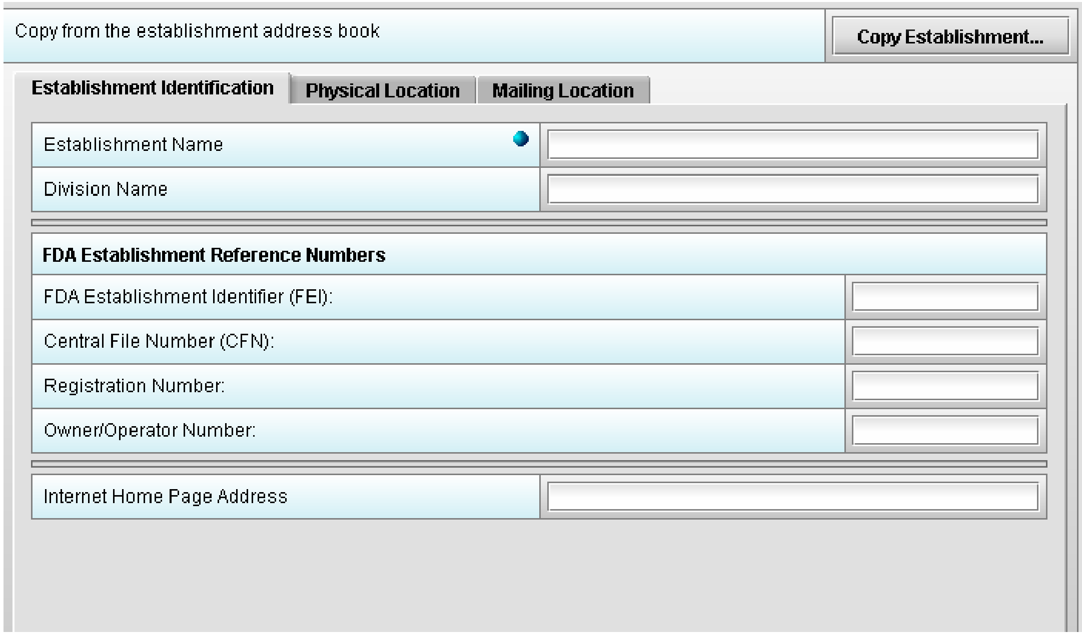


Figure 50: Example of an Establishment Question

(See a description of a contact questions on page 51. For more information about Establishment Address Books, see page 25.)

File Attachment – This question type allows you to attach a PDF file as a response. The question may contain a text editor that allows or requires you to type additional information. In addition, this editor may be an HTML Editor which allows you to format what you type (bold, underline), run spell check or insert a table. You may use this area to provide descriptive information or clarification, such as "see page 15 of the attached user manual." You may be required to enter the attachment or the descriptive text.

Attaching PDF files requires software capable of viewing and/or printing PDF files (e.g., Adobe Acrobat). The first time a PDF file is attached, the software will prompt you to locate the application within the system that will be used to view/print such files. (See *Figure 51*.) Once identified, the software will no longer prompt for this information. For information on setting up your PDF Viewer, see page 13. *Figure 52* shows an example of an attachment question with a response entered.

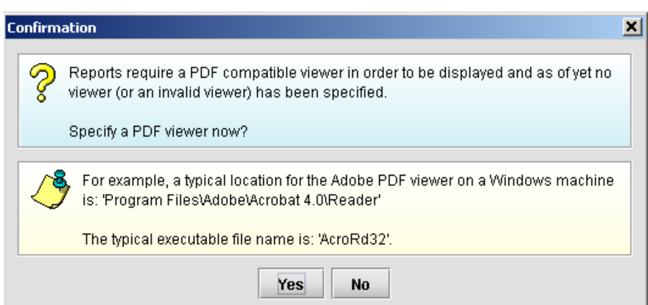


Figure 51: Confirmation Dialog Box

Note: You may only attach files that are PDFs; no other formats (such as Microsoft Word or Excel) are acceptable. **File names should not contain more than 250 characters. Do not use symbols when naming the files for attachments**. For example, do **not** use slashes (/) (\), tildes (~), asterisks (*), periods (.), brackets [ ], single quotation marks (‘), double quotation marks (“) or parentheses ( ). Once the file is attached to a question, it can be selected as an attachment to other questions, if appropriate.

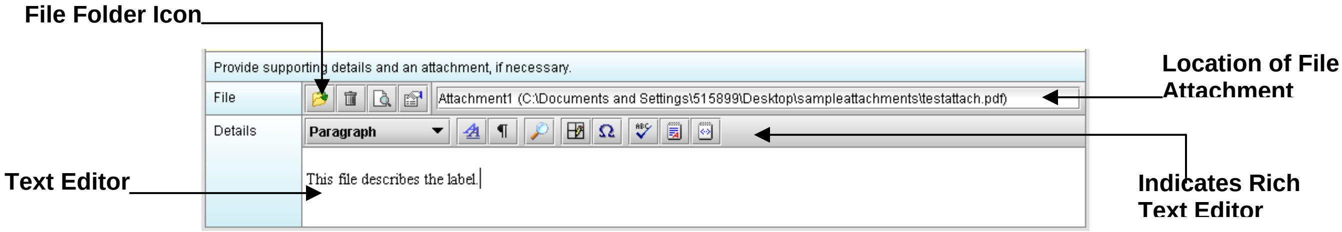


Figure 52: Example of an Attachment Question

To attach a PDF file to an attachment question:

1. Click the file folder icon to select the desired PDF file.
   You see a **File List Dialog** box.
2. Click to select the desired file (if it is listed).
   OR
   Click **Add** to place another file in the list. You see a **New File Dialog** box. An example is shown below.

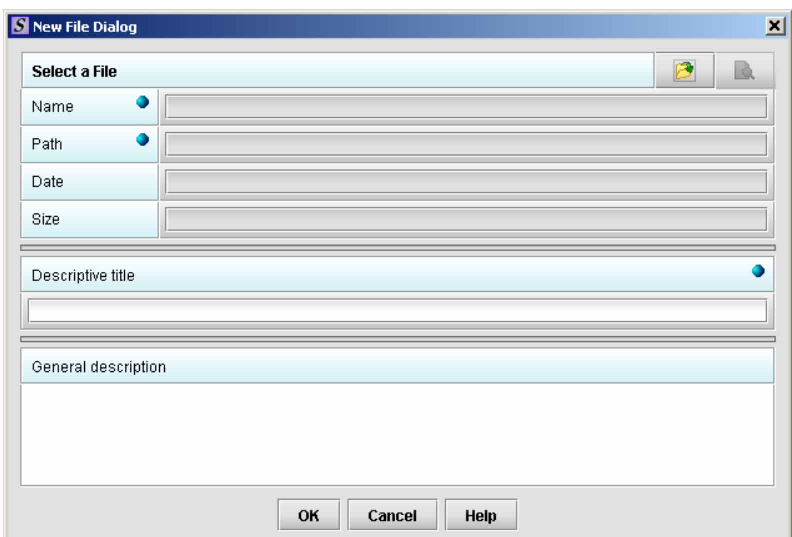


Figure 53: Example of a New File Dialog Box

- Click the open folder  button. You will see a **Select File** dialog box. An example is shown in *Figure 54*.

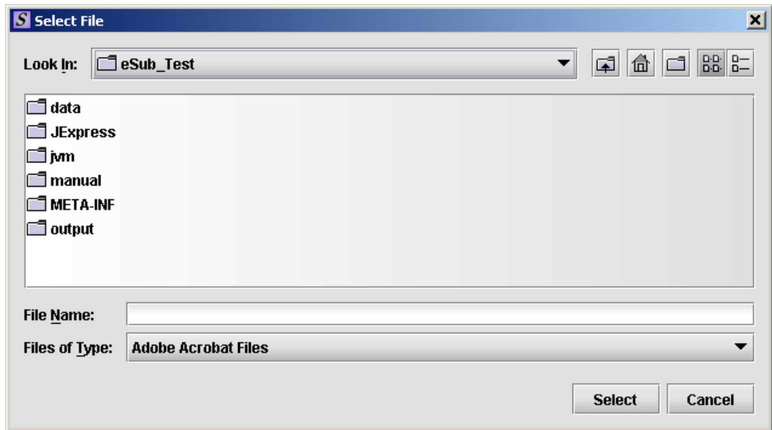


Figure 54: Example of a Select File Dialog Box

- Click in **Look In** to locate the drive, such as Local Disk (C:), or folder where the PDF is stored.
- When you locate the desired PDF, click to select it (highlight). The name of the file appears in **File Name**. An example is shown below.

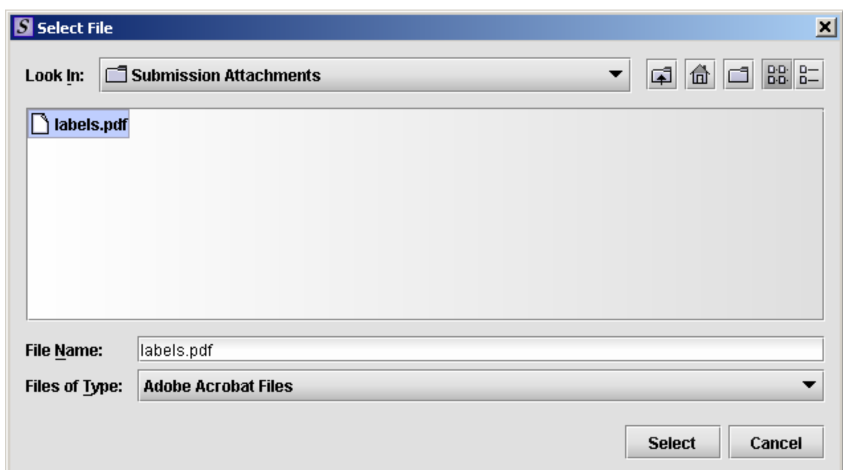


Figure 55: Example of a Selecting the Desired PDF

- Click **Select**. The **Select File** dialog box closes, and you return to **New File Dialog** box.
- Enter a title in **Descriptive title** (required entry) and a description in **General description**, if desired.
- Click **OK**. You return to the **File List Dialog** box. The PDF that you just added is automatically selected (highlighted).

3. Click **Select**.
   You see the path (location) of the file on the network drive or hard drive of your computer appear in the file attachment question.

Multiple File Attachments – This question type allows you to attach multiple PDF files as a response. *Figure 56* shows an example of an attachment question with a file attachment included.

Attaching PDF files requires software capable of viewing and/or printing PDF files (e.g., Adobe Acrobat). The first time a PDF file is attached, the software will prompt you to locate the application within the system that will be used to view/print such files. (See *Figure 51* for an example.) Once identified, the software will no longer prompt for this information. For information on setting up your PDF Viewer, see page 13.

Note: You may only attach files that are PDFs, no other file formats (such as Microsoft Word or Excel) are acceptable. Files may be used in more than one question. **File names should not contain more than 250 characters. Do not use symbols when naming the files for attachments**. For example, do **not** use slashes (/) (\), tildes (~), asterisks (*), periods (.), brackets [ ], single quotation marks (‘), double quotation marks (“) or parentheses ( ).

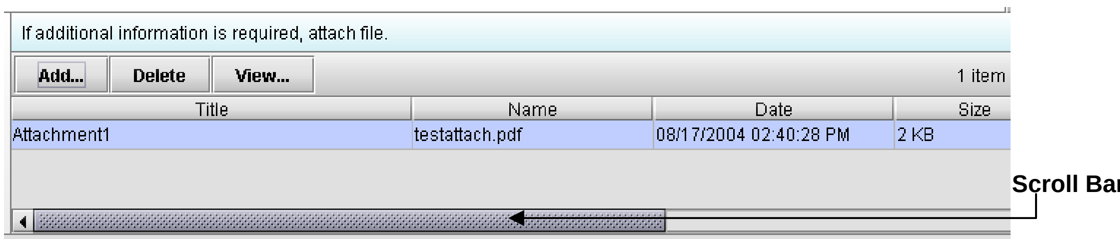


Figure 56: Example of a Multiple Attachment Question

To attach a PDF file to an attachment question:

1. Click **Add**.
   You see a **File List Dialog** box.
2. Click to select the desired file (if it is listed).
   OR
   Click **Add** to place another file in the list.
3. Click **Select**.
   You see information about the file appear.
4. To see additional information, use the scroll bar.
5. Click **Add** and repeat steps 2 and 3 to add another file attachment.
6. Repeat step 5 for each file that you wish to add.
   OR
   Click **Delete** to remove a file from the attachment question.
   OR
   Click **View** to see a PDF file in the list of files.

Guidance Documents – This question type allows you to select the guidance documents that you used to prepare your submission, as well as provides space for you to add supporting text if necessary. *Figure 57* shows an example of a guidance document question.

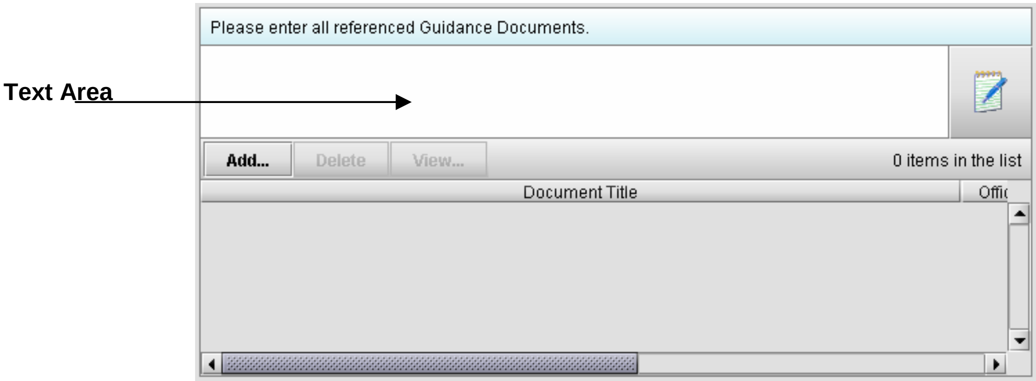


Figure 57: Example of a Guidance Document Question

To select a Guidance Document:

1. Click **Add**.
   You see a **Guidance Document Filter Dialog** box.
2. On this dialog box, you have several options for searching for a particular guidance document:
   - In the **Title** text box, you can type the title of the desired document (if you know what it is).
   - If you do not know the title of the document, select the applicable office from the **Office** list box.
   - On the **Division** list box, select the desired Division.
   - Click **Clear Filter** to delete your selections and begin a new search.

Depending on which method you used, one or more guidance documents will appear in the **Guidance Documents matching the specified filter criteria** area of the screen. *Figure 58* shows an example when CDRH is selected for the **Office** list box.

3. Use the scroll bar to see information about the found guidance documents.
4. If you are connected to the Internet and have Adobe Acrobat installed, click to select a desired document, and click **View Guidance** to see the selection.
5. To move a guidance document to **Guidance Documents currently selected** area of the screen:
   - Click to select (highlight) a particular guidance document.
   - Click **Select**. The selected document appears in **Guidance Documents currently selected** area of the screen.
   - Repeat the above two items for each desired guidance document. *Figure 58* shows an example of one selected document.
   - Click **Delete** to remove a guidance document from your selection.
6. Click **OK** when you have made your selections.
   You return to the guidance document question with your selection appearing. *Figure 59* shows an example of a guidance document question containing a response.

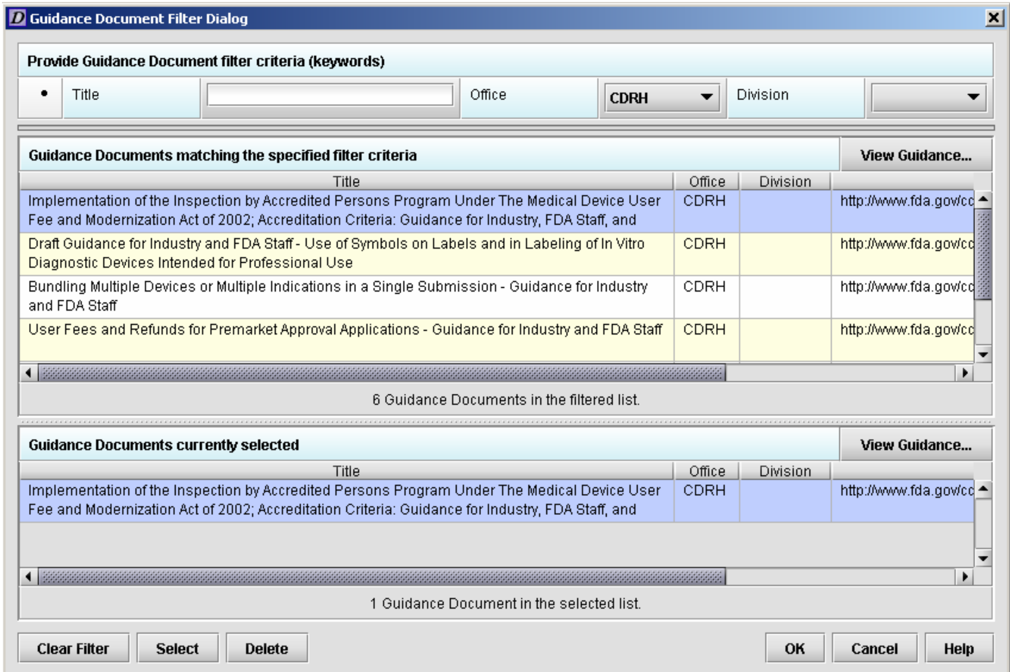


Figure 58: Example of the Guidance Document Filter Dialog Box

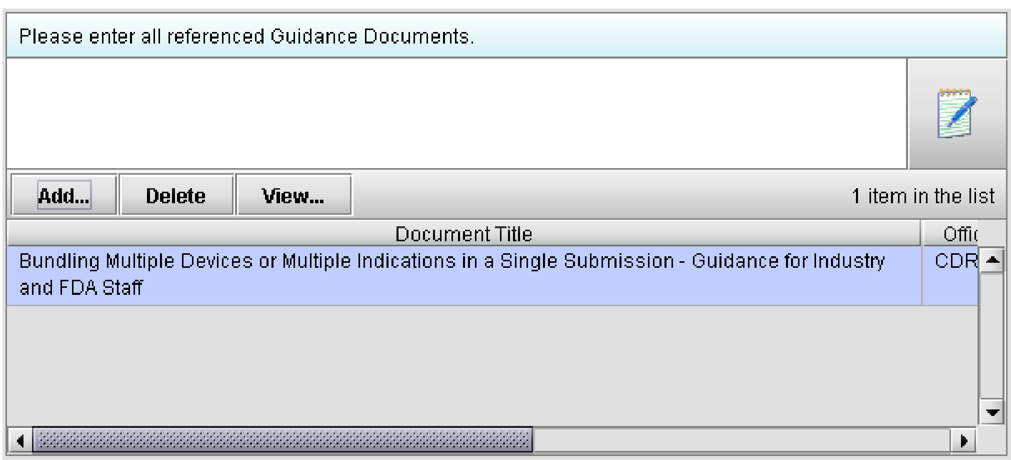


Figure 59: Example of a Guidance Document Question with Response

List Item – This question type allows you to select an item from a list of options. *Figure 60* shows an example of a list item question.

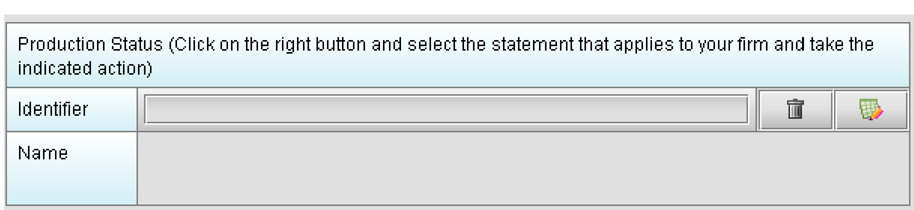


Figure 60: Example of a List Item Question

To access the list of available options:

1. Click the  (Change Table) button.
   You see a **Selections List Dialog** box. An example is shown below:

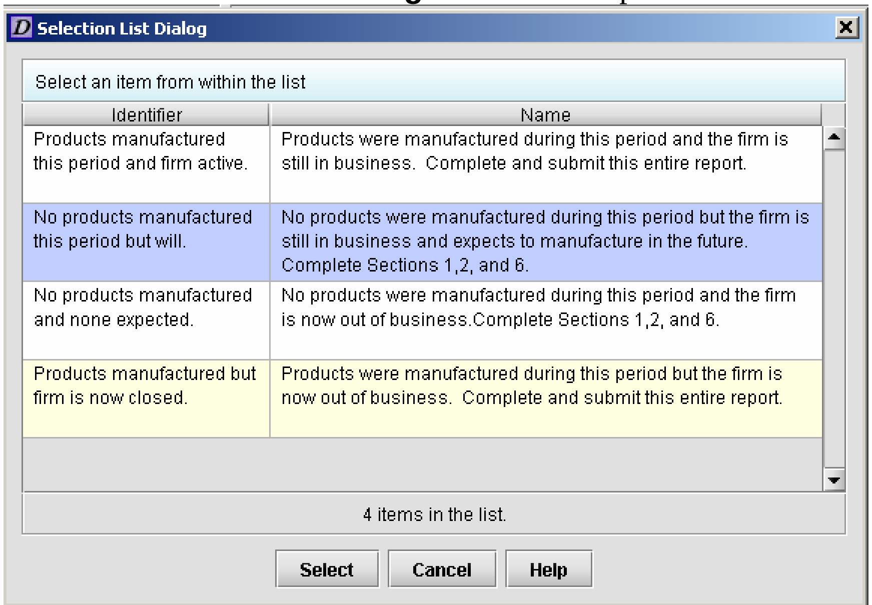


Figure 61: Example of a Selection List Dialog Box

2. Click to select (highlight) the desired option.
3. Click the **Select** button.
   The **Selection List Dialog** box closes, and you return to the open submission with the list item question showing your selection. An example is shown below:

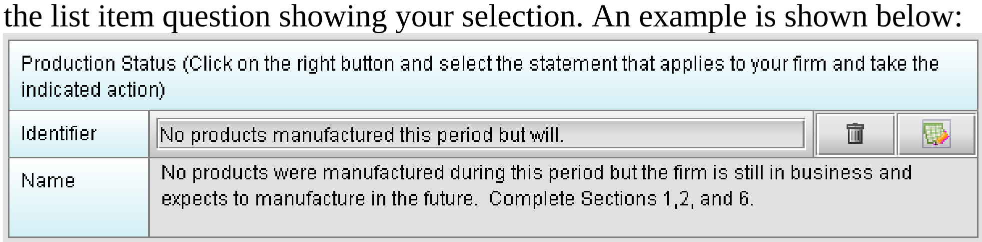


Figure 62: Example of a List Item Question Containing a Response

- If you wish to change your response, click the button with the trash can item. Your response selection is deleted from the question.
- Repeat steps 1 through 3 to make another selection.

Memo (Multi Line Text) – This question type provides an area for you to enter several lines of text. See *Figure 63* . The question may contain a Rich Text Editor which allows you to format what you type (bold, underline), run spell check or insert a table. The tool bar for the Rich Text Editor will appear after you click in the text area to begin typing. Figure 64 shows an example of a multi-line question with a rich text editor. See also *Text, Single Line* question type on page 64.

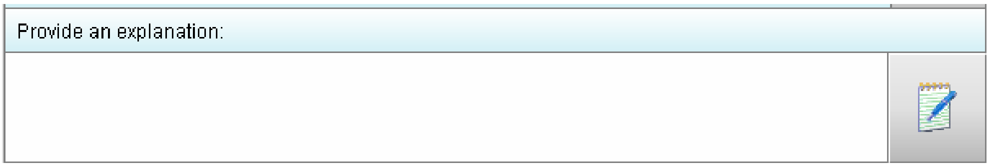


Figure 63: Example of a Multi-Line Text Question

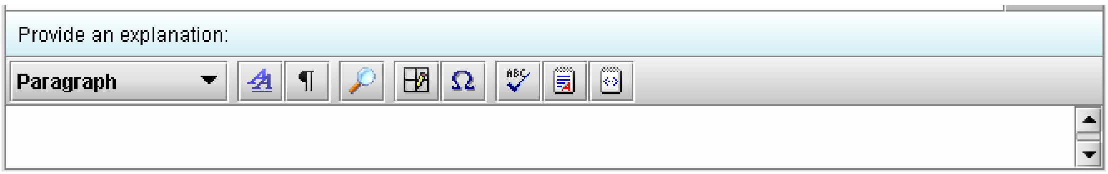
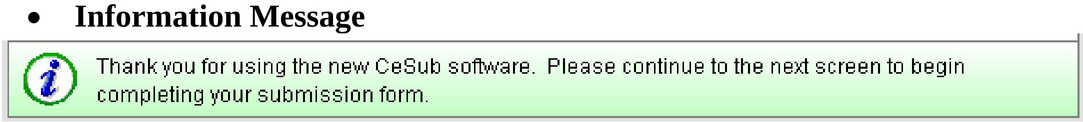


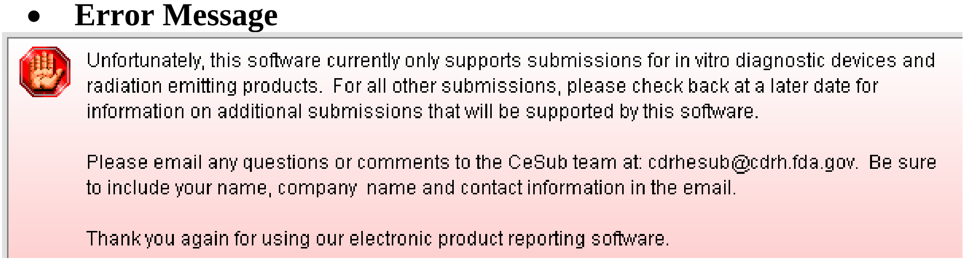
Figure 64: Example of a Multi-Line Text Question with a Rich Text Editor

Message – This question type provides information to you as you complete a submission. You may see several different types of messages as you progress through your submission. Different examples of the message types are listed below:

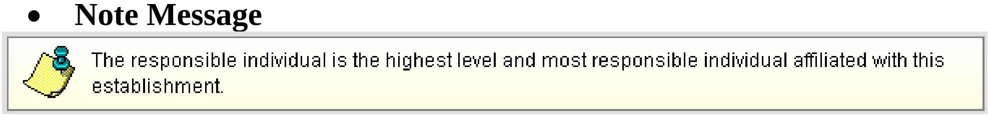
- **Information Message**



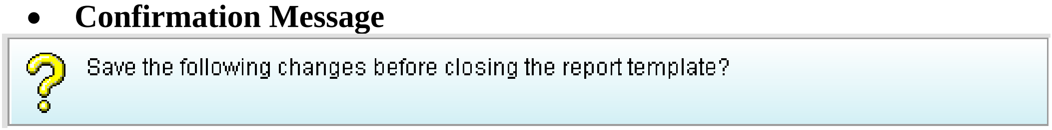
- **Error Message**



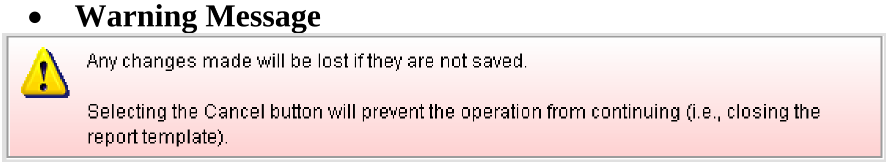
- **Note Message**



- **Confirmation Message**



- **Warning Message**



Product Code (Single) – This question type allows you to search for and then identify the product code that is assigned to your product or device. If applicable, you are able to search for the device class, device panel and particular CFR section. The response to this question is for a single product code. *Figure 65* shows an example of a product code question.

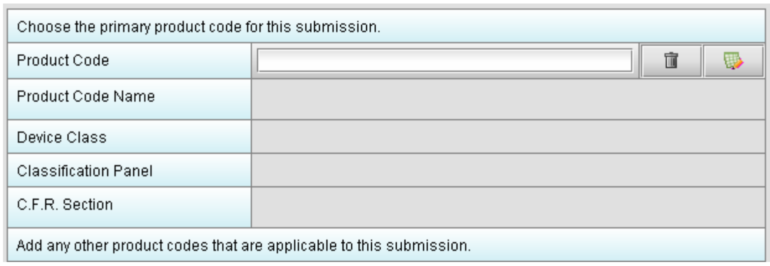


Figure 65: Example of a Single Product Code Question

To enter a three-letter code in the product code question:

- If you know the three-letter code assigned to your product/device, enter it in the text box. The remaining fields are automatically filled in for you.
- If you wish to remove your entry, click the trash can icon.
- If you do not know the three-letter code, see the instructions below to search for the code.
- If you are selecting a product code for a radiation emitting product and do not see an appropriate code, enter **RZZ**.

To search for a three-letter code by keyword:

1. Click the  (Change Table) button (located next to the trash can).
   You see a **Product Code Filter** dialog box. *Figure 66* shows an example:

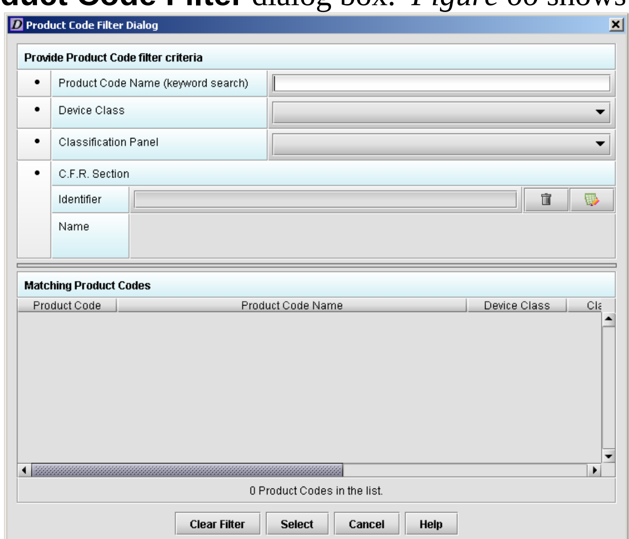


Figure 66: Product Code Filter Dialog

2. Enter a keyword to search the database. You will be provided a list of product codes from which to choose in the **Matching Product Codes** portion of the dialog box.

3. To further refine your search, **if desired** (see *Figure 67*):
   - Click the **Device Class** drop-down list and make a selection.
   - Click the **Classification Panel** drop-down list and make a selection.
   - Click the **CFR Section**  icon and make a selection.

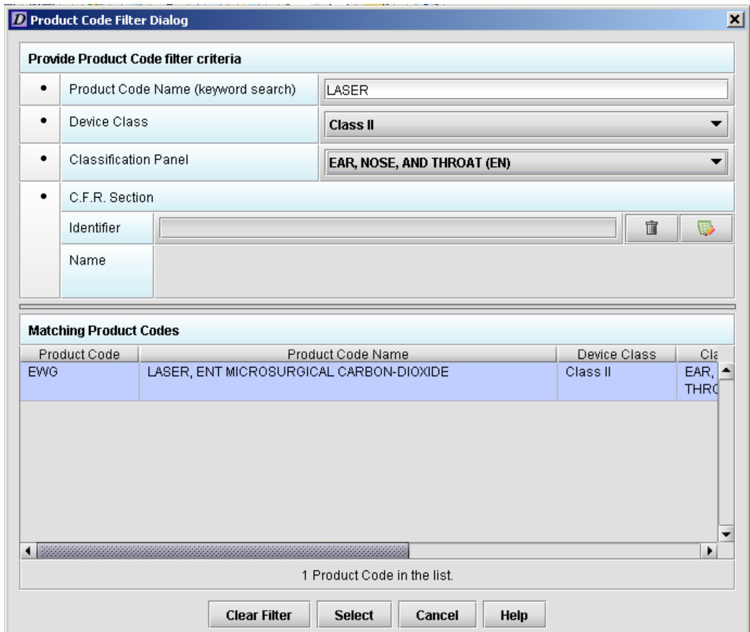


Figure 67: Refining a Product Code Search

   - Click **Clear Filter** to remove entries and start the search over again.

4. Click to highlight the best match to your product/device, and click **Select**. You return to the submission screen and the product code question. The remaining fields in the product code question are filled in for you. See *Figure 68* for an example.

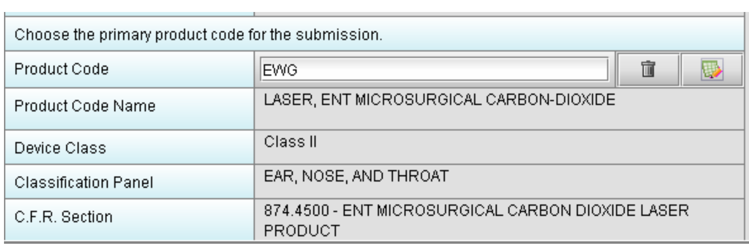


Figure 68: Product Code Response

Product Codes (Multiple) – This question type allows you to identify other product codes applicable to the submission. *Figure 69* shows an example of a multiple product code question.

Figure 69: Example of a Multiple Product Code Question

To add product codes:

- Click **Add**. You see the **Product Codes Filter Dialog** box (as shown in *Figure 70*).

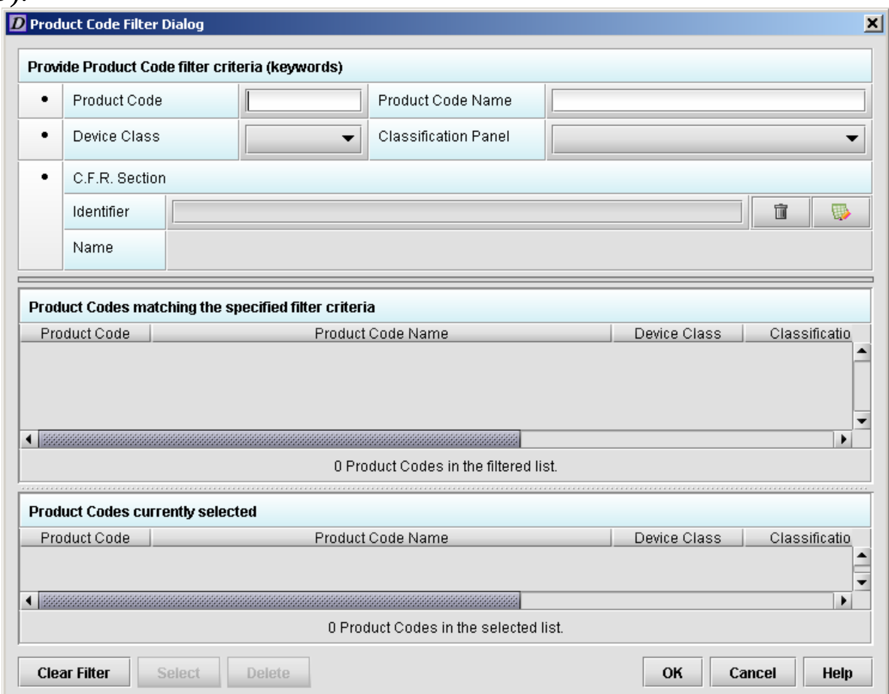


Figure 70: Example of a Multiple Product Code Question

To enter a three-letter code in the product code question:

1. If you know the three-letter code assigned to your product/device, enter it in the **Product Code** text box. You see the product code/device appear in **Product Codes matching the specified filter criteria**.
2. Click **Select**. The product/device appears in **Product Codes currently selected**.
3. Repeat steps1 and 2 to continue to add product codes.

   OR

   - If you do not know the three-letter code, see the instructions below to search for the code.

   OR

   - Click **OK** to return to the multiple product codes question.

To search for a three-letter code by keyword:

1. Enter a keyword in **Product Code Name** to search the database. You will be provided a list of product codes from which to choose in the in **Product Codes matching the specified filter criteria** portion of the dialog box.
2. To further refine your search, if desired:
   - Click the **Device Class** drop-down list and make a selection.
   - Click the **Classification Panel** drop-down list and make a selection.
   - Click the **CFR Section** icon and make a selection.
   - Click **Clear Filter** to remove entries and start the search over again.
3. Click to highlight the best match to your product/device, and click **Select**. The product/device appears in **Product Codes currently selected**.
4. Repeat steps1 and 2 to continue to add product codes.
   OR
   Click **Delete** to remove a product code from the selection.
5. Click **OK** to return to the multiple product codes question, which shows your selections.

Standards – This question type allows you to select a standard for your submission from the CDRH list of recognized standards. *Figure 71* shows an example of a standards question.

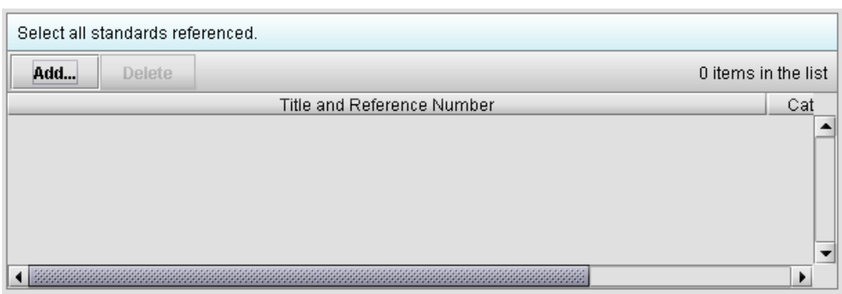


Figure 71: Example of a Standards Question

To add a standard:

1. Click **Add**. You see the **Standards Filter Dialog** box (as shown in *Figure 72*).

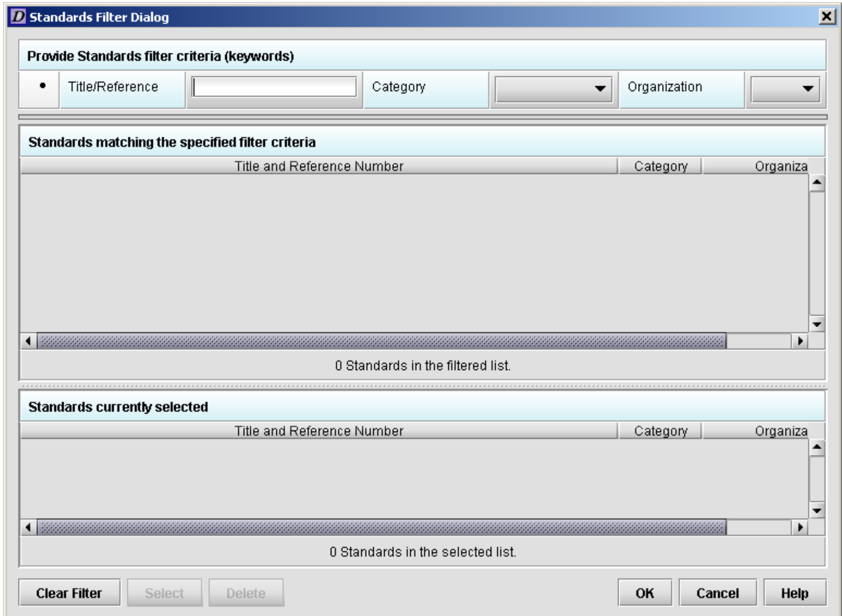


Figure 72: Standards Filter Dialog Box

2. Enter a title in **Title Reference** (if known) to search the database.
3. To further refine your search, if desired:
   - Click the **Category** drop-down list and make a selection.
   - Click the **Organization** drop-down list and make a selection.
   - Click **Clear Filter** to remove entries and start the search over again.
4. Click to highlight the best match to your product/device, and click **Select**. The standard appears in **Standards matching the specified filter criteria**.
5. When you are finished adding standards, click **OK**. You return to the standards question.

Table – This question type allows you to select from a list or add text items that are then placed in a table. *Figure 73* shows an example. To make selections, click **Add**.

Figure 73: Table Question

Text, Single Line – This question type allows you to type in text as a response. *Figure 74* shows an example of a text question.

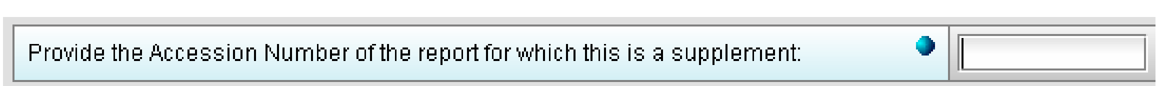


Figure 74: Example of a Text Question

Sections as Tables – Entire sections may appear as a table. This format is indicated by a row of buttons for **New**, **Delete**, an up arrow and a down arrow. Directly below this row of buttons is the actual table. You also see a **List** and **Details** tabs. Click the **New** button to add an item to the table. You see a screen containing questions for you to answer. To see the items on in the table, click **Details**. If you accidentally enter a blank into the table, (by clicking **New**, not responding to any questions, and then clicking **Details**), you will see a line of colored blank spaces. Select the line of colored spaces and click the Delete button to remove the item from the table.

5.2.2 Entering Responses into the Submission

To enter information into the submission:

1. The CeSub eSubmitter application must be open on your computer desktop, and a submission must be open.
   If the application and a submission are not open, see the instructions beginning on page 43.
2. Navigate through the submission as follows:
   - If you are in the simple layout, use the buttons on the button bar to advance to next/return to previous screen.
   - If you are in the expert layout, use the outline section, and activate each section to load the questions.
3. Provide a response to the question(s) on the screen. The response required depends on the type of question. For information on the different question types, see page 48.
4. Save your responses periodically. For information, see *Saving Submission entries or Changes*, beginning on page 65.

5.3 SAVING SUBMISSION ENTRIES OR CHANGES

While moving through the submission, any changes made to question responses are automatically updated within memory (e.g., the user made a change to a question response, went to another section of the submission, and returned to see that the changes to the response were still in effect). If you have auto-save turned off in **Preferences**, these changes are only saved permanently when you select the **Save** option from the tool bar or **File** menu. Therefore, follow the same guidance that you would use when saving data in other software. In other words, whenever you have entered an amount of data that would be frustrating to have to re-enter, select the save option. For information on changing auto-save preferences, see page 18.

Note: The software will remind you to save if data has been changed and you are about to perform an operation that would result in losing your changes, such as opening another submission or exiting the application.

To save a submission:

- Click **File > Save**.
  OR
- Click .on the tool bar

You may not finish entering information into a submission in one session, so you may return to it at another time. See *Closing and Reopening an Existing Submission*.

5.4 CLOSING AND REOPENING AN EXISTING SUBMISSION

To close a submission:

1. Save the open submission before you close it:
   - Click **File > Save** on the menu bar.
     OR
   - Click  on the tool bar.
2. Click **File > Close**.
   The General Screen is displayed.

To re-open an existing submission:

1. Click **File > Open** on the menu bar.
   OR
   Click  on the tool bar.
   You see the **Open Report Dialog** box.
2. Click to select (highlight) the submission that you wish to open, and click **Select**.
   The selected report is displayed.
3. When you have entered all the required information into the report, you are ready to complete the submission. See *Completing a Submission*, beginning on page 67.

<u>Note:</u> The CeSub eSubmitter software is continually being updated and improved. Therefore some of the forms, referred to as "templates," that you fill out are changed. So, if you started to complete a submission several months ago, but you have not completed it and the form ("template") has been updated, you may see a warning when you open the submission. The warning states that you have 30 days to complete your submission before the template becomes inactive. This means that you should complete your submission as soon as possible because after 30 days, you will no longer be able to save any changes that you make to your submission. If you try to make changes after the form ("template") becomes inactive, you will see a warning stating that the changes cannot be saved. An example is shown in *Figure 75*.

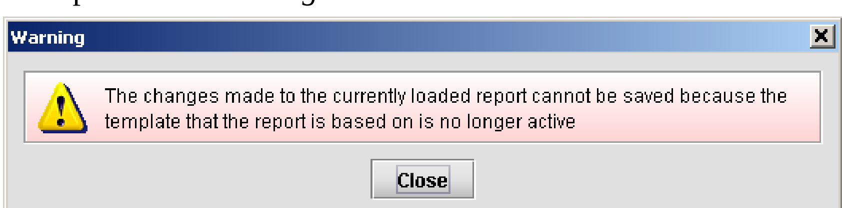


Figure 75: Example of an Inactive Template Warning

5.5 COMPLETING A SUBMISSION

To complete a submission, you must identify if any data is missing from your report (and then enter the required data), package the files for submission, find the necessary files on your computer, and copy the files onto a CD.

5.5.1 Missing Data

You will only be able to package files for submission as long as no required data is missing from the submission. To determine if any data is missing, you will generate a Missing Data Report. To proceed, the desired submission should be open and displayed on your computer screen.

Note: All report outputs are generated as HTML and require an application capable of viewing HTML output, such as a WEB browser, the full version of Adobe Acrobat (not Acrobat Reader), or Microsoft Word.

To determine if required data is missing from the submission:

1. From the menu bar, click **Output >Missing Data**. (See also page 24.)
   You see the **Report Output Dialog** box as shown in *Figure 76.*

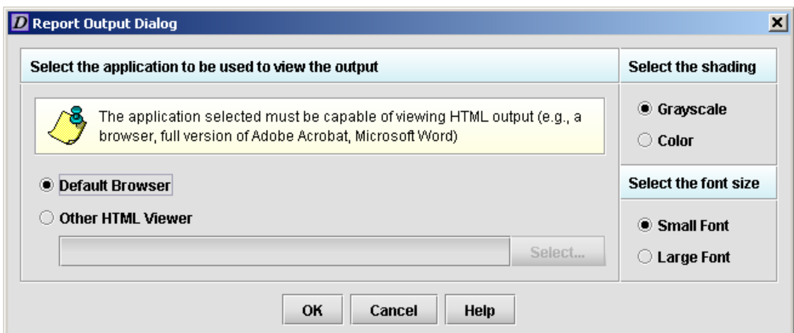


Figure 76: Example of a Report Output Dialog Box

2. On this dialog box:
   - Select the desired application to view the output in HTML:
     Click the option button: **Default Browser** or **Other HTML Viewer** (The default setting is your Web Browser.)
     - ⇒ If you selected **Other HTML Viewer**, the **Select** button becomes enabled. Click the **Select** button. You see the **Select HTML Viewer Application File** dialog box, as shown in *Figure 77*.

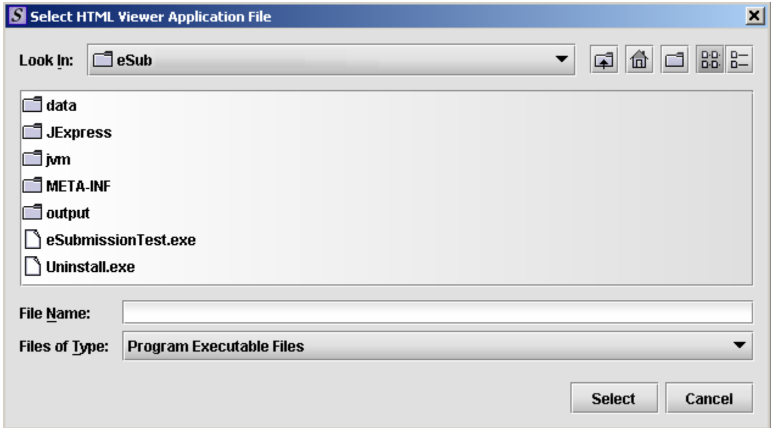


Figure 77: Example of Select HTML Application File Dialog Box

⇒ Click in the **Look In** box to navigate to the **executable** (.EXE) of the application to view the HTML. For example, if you want to view the missing data output report in Word 2002, you would navigate using the following path:

C: > Programs > Microsoft Office > Microsoft Office > Office 10> WINWORD.EXE

The following screens (display an example for the navigation sequence to find Word 2002's executable (winword.exe).

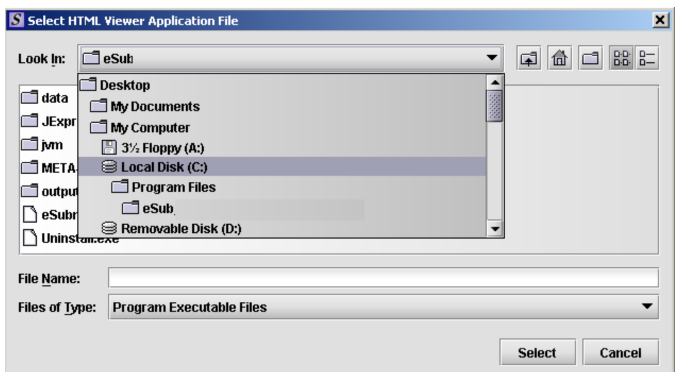


Figure 78: Finding Word's Executable File (Navigation 1)

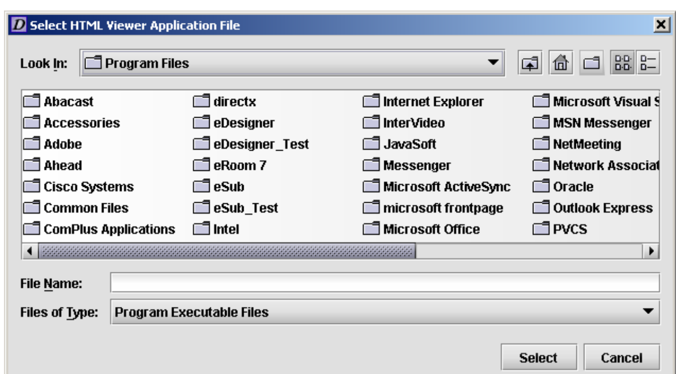


Figure 79: Finding Word's Executable File (Navigation 2)

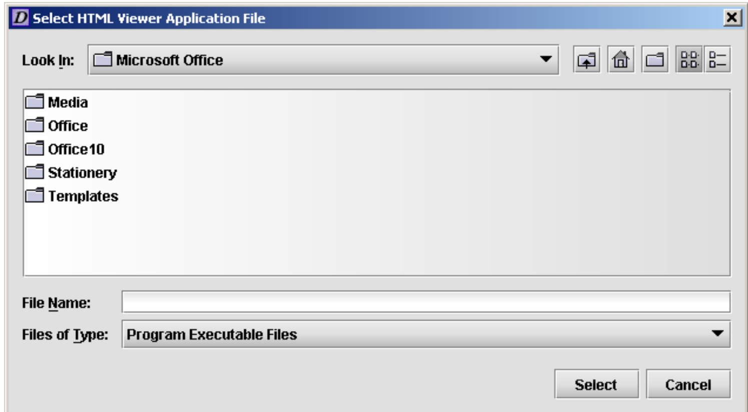


Figure 80: Finding Word's Executable File (Navigation 3)

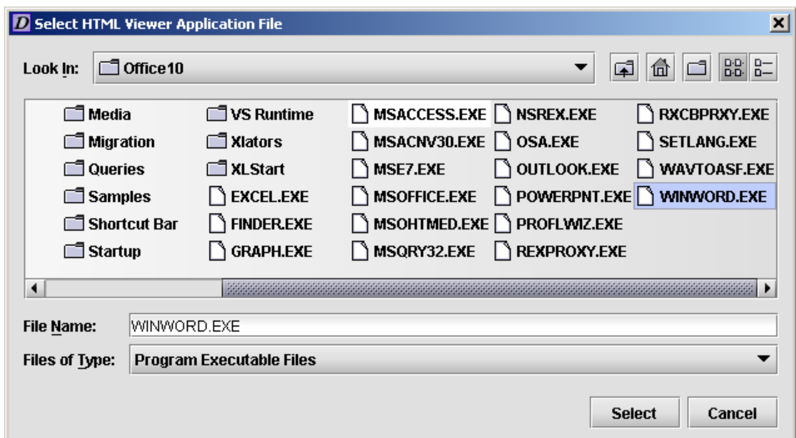


Figure 81: Finding Word's Executable File (Navigation 4)

⇒ Click **Select**. You return to the **Report Output Dialog** box with your selection showing. An example is shown below.

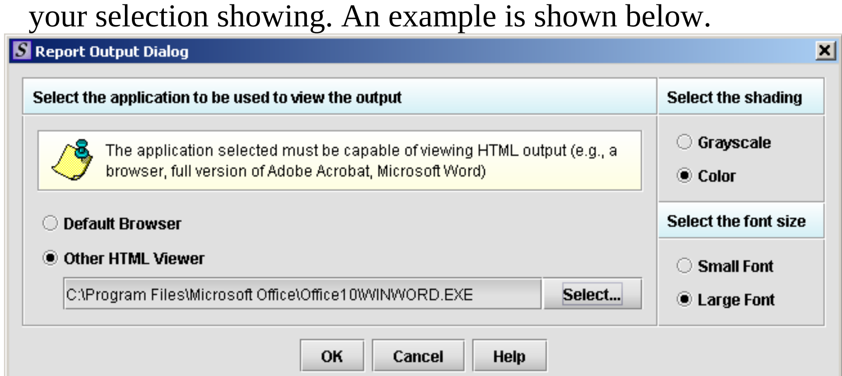


Figure 82: Report Outlook Dialog with Word selected

- Select the desired shading of the report:
  Click the option button for **Grayscale** or **Color**.
- Select the desired font size:
  Click the option button for **Small Font** or **Large Font** (which is approximately 10 pt).

- When you are finished making selections, click **OK**.

The eSubmitter software generates the report in HTML, which opens for viewing in the application that you selected. The missing data output report will either state that there is no data missing (see *Figure 83*), or identify the missing data that must be entered before the files are packaged for submission.

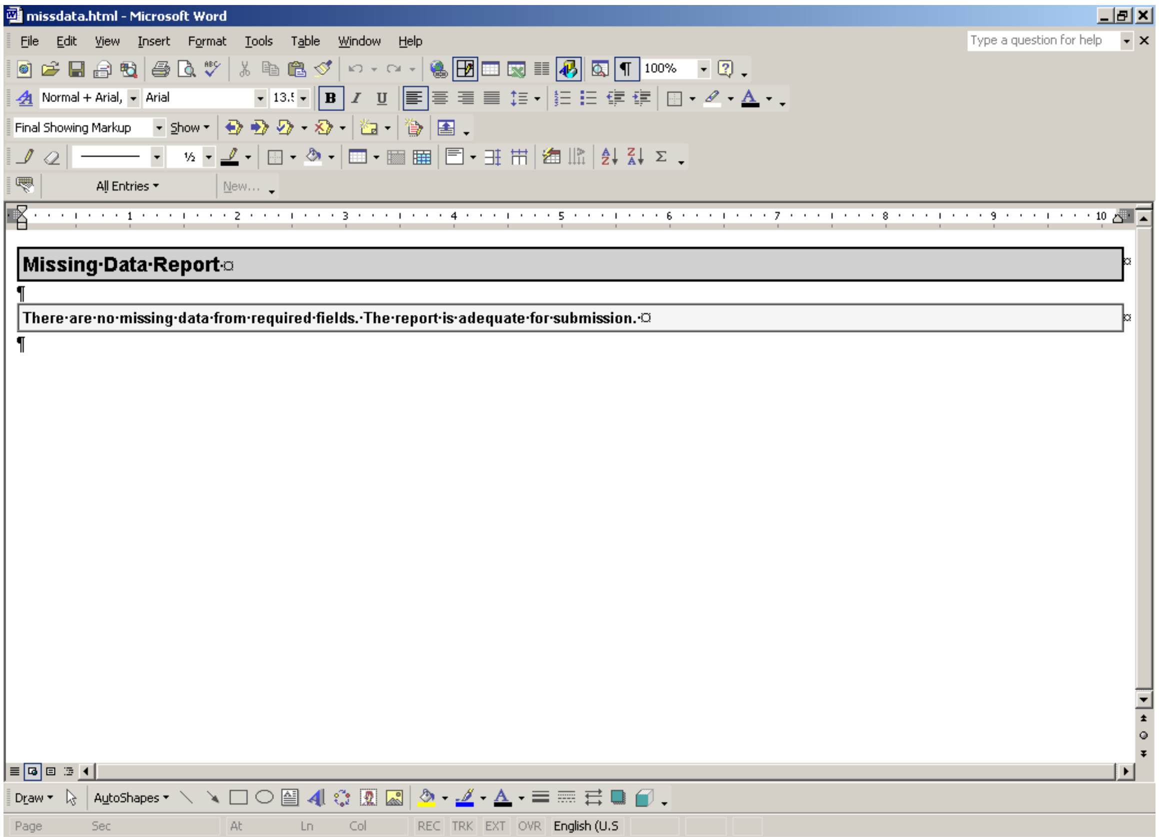


Figure 83: Example of Using Word For Viewing A Missing Data Report

3. After you have verified that no data is missing from the submission, you are ready to package your files for submission.

5.5.2 Packaging Submission Files

After completing the submission and verifying there is no information missing, you are ready to package the files for submission. To proceed, you should have the eSubmitter application open, and the finished submission displayed on your computer screen.

To package the files for submission:

1. From the menu bar, click **Output > Package Files for Submission**. (See also page 24.)
   - If you have missing data, you see the warning shown in *Figure 84*:

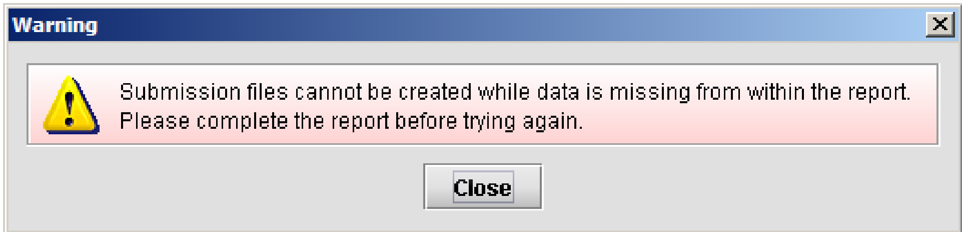


Figure 84: Missing Data Warning

- If the submission has all required data, you see the **Package Files for Submission Dialog** box (an example is shown in *Figure 85*):

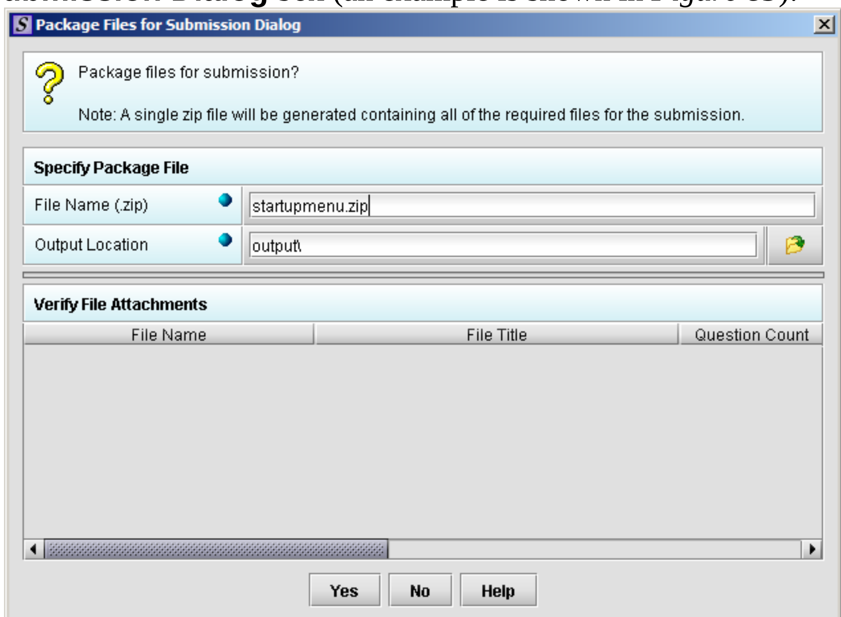


Figure 85: Package Files for Submission Dialog Box

2. On the **Package Files for Submission Dialog** box:
   - The **File Name (.zip)** text box identifies the default zip file name for the submission. (eSubmitter automatically uses the submission name for the zip file.) Make a note of the name for the zip file. **Do not modify the zip file after it is generated by eSubmitter.**
   - The **Output Location** identifies the default file folder where the zip file is located. (If you did not change the location of the eSubmitter software when you installed it, the output location is c: Program Files\eSub\output). Make a note of the output location.
     ⇒ To change the location click the file folder icon, locate the desired location, and click **Select**.
   - **Verify File Attachments** lists all file attachments used in the submission.
     ⇒ Check the list to make sure that all of the appropriate file attachments are listed (only files referenced in responses will be included. Check the question counts for confirmation).
     ⇒ Check the file dates, size and locations to ensure the correct versions of the files are provided.
3. When you have checked the file name, output location and file attachments:

- Click **Yes** to close the dialog box and attempt to package the files for submission. If any problems occur, a dialog box appears to explain the issue. Once completed, an informational dialog box will display the names and locations of the files that were generated. An example is shown in *Figure 86.*

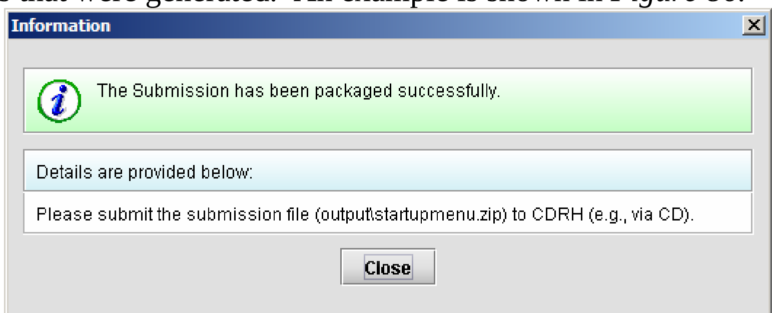


Figure 86: Information Dialog Box for Submission File

  ⇒ Click **Close**. You return to the open submission.
- Click **No** to close the dialog box without packaging the files for submission.
- Click **Help** to display the help window and help text.

4. You are ready to locate the files on your computer, print out pages and copy the files onto a CD. **Do not modify the zip file after it is generated by eSubmitter.**

5.5.3 Printing, Locating, and Copying Files

After packaging the files for submission, you need to find the files on your computer and copy them onto a CD. In addition, you will need to print out the submittal letter (and sign it). For an OIVD submission, the truth and accuracy statement is part of the letter.

To proceed, you should have the eSubmitter application open, and the finished submission displayed on your computer screen.

To print the submittal letter from your submission:

1. From the menu bar, click **Output > Print Submittal Letter**
   You see the **Report Output Dialog** box.
   - On this dialog box:
     ⇒ If you created a Missing Data Report, your selection for the HTML viewer is retained. If you wish to change the selection or if you did not create the Missing Data Report, see the instructions on page 67, beginning with step 2 to select the HTML viewer.
     ⇒ After you selected the HTML viewer, click **OK**.
   - The eSubmitter software generates the submission letter in HTML, which opens for viewing in the application that you selected. Print out the submittal letter and sign it.
2. Close the submission (from the menu bar, click **File > Close**).
3. Exit from the eSubmitter software (from the menu bar, click **File > Exit**).
4. Locate the submission files on your computer, using the instructions below.

<u>Note:</u> If you re-package your submission for any reason, be sure to print out a new submittal letter, sign it, and include with the CD that you send to CDRH.

To locate the submission files on the computer's hard drive:

1. Use Windows Explorer to navigate to the label for the computer's installed hard drive, e.g., **Local Disk (C:)**. For example, on a computer with Windows 2000:
    - Open Windows Explorer.
    - Double-click **My Computer** to display its contents.
    - Look for the label of the computer's installed hard drive. For example, **(C:)**.
2. Double-click on the label for the hard drive to display its contents.
3. Navigate to and double-click to open the **Program Files** file folder.
4. Navigate to and double-click to open the **eSub** file folder.
5. Double-click to open the **output** file folder.
   You see the zip file that you created in *Packaging Submission Files*, beginning on page 70. **Do not modify the zip file after it is generated by eSubmitter.**
6. Copy this file onto a CD.
7. Mail the CD and signed cover letter to the address provided in your submission.

6. GETTING SUPPORT

For technical assistance for the CeSub eSubmitter software, please contact us at cdrhesub@cdrh.fda.gov. In the email, please provide the company name and contact information where a response can be sent.

7. FREQUENTLY ASKED QUESTIONS

(1) The software requires Windows OS, Adobe Reader 5.0 (or full Adobe Acrobat), and a CD-R. Does it require any special permissions for a user on a Win2K/WinXP machine? What exactly does jinstall.exe unpack?

The CeSub application is based on Java. The installation program will unpack the application into the user designated location. All files installed will reside in the aforementioned designated location. The files installed include the application and support files, a Java runtime engine (JRE 1.4.2), and install/uninstall information. The JRE installed is specific to this application and should not interfere with other possible JRE's installed (i.e., it's not recognized by the OS but instead called by the CeSub application directly). The install program will setup menu short-cuts as well as provide uninstall information to the OS, which will require access to the Windows registry. Otherwise, no additional permissions should be required.

(2) Does this program introduce any new DLLs?

No.

(3) Does it require any specific version of DLLs that are standard on the machine?

No.

(4) Does it communicate outside the local box? Does it use any TCP ports?

Yes. The application uses an internet connection to perform auto-updates of the application and support files (e.g., enhancements, fixes). The auto-update process is called at start-up every time the application is executed. However, if no internet connection is available the application will still execute fine but no updates will be received. If you use a proxy server there are settings within a configuration of the application to give the application permission to contact its auto-update site.

(5) Does it introduce any vulnerabilities that you (the developers) are aware of?

None that we are aware of.

(6) Are there any issues I should be aware of that might affect our environment?

None that we are aware of.

(7) Can I install the software on a network?

Yes. The software can be installed anywhere and will work properly. A new file locking option has recently been added to the software that you set to prevent users from accidentally overwriting the work of another. For details, see *Networking* in *Preferences* on page 20.

(8) I have a PDF that I want to include. Can I add it the winzip file generated by eSubmitter?

No. Do not modify the file after it is generated by eSubmitter. If you do, your submission will fail our loading process. You will have to repackage your files and resubmit your submission to CDRH. Always attach the desired PDF to the appropriate question.

(9) I sent my submission to CDRH, but was notified by a CeSub team member that something was wrong with my submission. I fixed the problem, repackaged the submission, and created a new CD. Is that all I have to do?

No. Be sure to print out a new submittal letter, sign this new letter and include with your resubmittal.

8. INDEX